Wombat Trials Booklet 2012

Australian randomised trials in maternal and perinatal health

Studies currently recruiting or yet to start recruiting as at February 2012

WOMen and Babies Health and Wellbeing: Action through Trials

www.wombatcollaboration.net
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Foreword

The WOMBAT Collaboration is delighted to present the sixth edition of the WOMBAT Trials Booklet in its role in supporting maternal and perinatal trials in Australia. The WOMBAT Collaboration was funded through a NHMRC enabling grant (349570) to promote and support high quality maternal and perinatal randomised clinical trials in order to improve the health and wellbeing of women and their children. One of the aims of the WOMBAT Collaboration is to identify national research areas and encourage appropriate clinical and methodological trials.

With 81 trials currently recruiting or due to start recruitment soon (53 in pregnancy and childbirth and 28 in neonatology) there continues to be a substantial increase in the number and diversity of maternal and perinatal trials in Australia. Over 20 maternal and perinatal trials have completed recruitment in the last 12 months. About 30 new maternal and perinatal trials are added to our website each year. Details of all maternal and perinatal trials in the WOMBAT cohort collected since 2003 (including recently completed ones) can be found on the WOMBAT Collaboration website (www.wombatcollaboration.net) and from the Australian and New Zealand Clinical Trials Registry (www.anzctr.org.au).

We trust that you find the information in this latest WOMBAT Australian randomised trials in maternal and perinatal health book useful. We know that some of you will be inspired to plan more trials in the many areas where high quality information is lacking. We hope that many of you will be enthused to join existing trials needing more centres to complete recruitment (please see the pages marked).

Professor Caroline Crowther
The WOMBAT Collaboration
Pregnancy and Childbirth Trials
A*STEROID

Title: Australasian Antenatal Study To Evaluate the Role Of Intramuscular Dexamethasone versus betamethasone prior to preterm birth to increase survival free of childhood neurosensory disability: a randomised controlled trial

ACTRN12608000631303

Trial Question: To determine whether giving antenatal dexamethasone to women at risk of preterm birth at less than 34 weeks gestation increases the chance of their children surviving free of neurosensory disability at 2 years corrected age, compared with women given antenatal betamethasone.

Treatment Groups: Intramuscular dexamethasone vs betamethasone prior to preterm birth.

Trial Status: Currently recruiting

Multi Centre: Australia and New Zealand

Additional Centres Needed: Yes

Recruitment Target: 1499

Recruitment as at February 2012: 921 women 1035 babies

Coordinating Centre: Australian Research Centre for Health of Women and Babies (ARCH), The University of Adelaide

Centres in Australia Currently Recruiting:
- SA – Women's and Children's Hospital
- Gawler Hospital
- Lyell McEwin Hospital
- NSW – Royal Hospital for Women
- Royal North Shore Hospital
- St George Hospital
- Nepean Hospital
- QLD – Ipswich Hospital
- Mater Mothers’ Hospital
- Townsville Hospital
- VIC – Royal Women’s Hospital
- TAS – Royal Hobart Hospital
- Launceston Hospital
- NZ - Auckland City hospital

Chief Investigators:
Professor Caroline Crowther, Professor Jane Harding, Philippa Middleton, Dr Chad Andersen, Emeritus Professor Jeffrey Robinson

Trial Contact:
Professor Caroline Crowther

Contact Details:
ARCH, The Robinson Institute
Discipline of Obstetrics & Gynaecology
The University of Adelaide
Women's & Children's Hospital
72 King William Road
North Adelaide SA 5006
Tel: +61 8 8161 7767
Fax: +61 8 8161 7652

Trial Coordinator:
Ms Pat Ashwood

Trial Email:
asteroid@adelaide.edu.au
A comparison of fentanyl with pethidine for pain relief during childbirth

**Title:** A comparison of fentanyl with pethidine for pain relief during childbirth

ACTRN12609001027202

**Trial Question:** Does fentanyl (administered intranasally, or subcutaneously) improve mother and baby outcomes compared with intramuscular pethidine?

**Treatment Groups:**

<table>
<thead>
<tr>
<th>Group 1</th>
<th>Self administered intranasal fentanyl, under supervision of a midwife</th>
</tr>
</thead>
<tbody>
<tr>
<td>Group 2</td>
<td>Fentanyl administered subcutaneously for pain relief</td>
</tr>
<tr>
<td>Group 3</td>
<td>Pethidine administered intramuscularly for pain relief</td>
</tr>
</tbody>
</table>

**Trial Status:** Currently recruiting

**Multi Centre:** Yes

**Recruitment Target:** 150

**Recruitment as at February 2012:** 57

**Coordinating Centre:** Flinders University / Women's & Children's Hospital/ Inner North Country Health SA

**Chief Investigator:** Julie Fleet

**Trial Contact:**

Julie Fleet

**Contact Details:**

GPO Box 2100
Adelaide SA 5001

Tel: +61 8 8201 2071

**Trial Email:**

degr0013@flinders.edu.au
A double-blind randomised controlled trial of oxytocin bolus plus placebo infusion versus oxytocin bolus plus oxytocin infusion for the prevention of uterine atony and post partum haemorrhage at elective caesarean section

ACTRN12607000631404

**TRIAL QUESTION:** To compare the efficacy of two intravenous (IV) oxytocin (Syntocinon®) regimens for the management of the third stage of labour in otherwise healthy women with a singleton pregnancy undergoing an elective lower segment caesarean section at term

<table>
<thead>
<tr>
<th>Treatment Groups:</th>
<th>A slow bolus intravenous injection of 5 iu oxytocin (Syntocinon®) versus a slow bolus intravenous injection of 5 iu oxytocin (Syntocinon®) plus 20 iu oxytocin (Syntocinon®) infusion.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Trial Status:</td>
<td>Currently recruiting</td>
</tr>
<tr>
<td>Single Centre</td>
<td>Southern Health: Monash Medical Centre &amp; Dandenong Hospital</td>
</tr>
<tr>
<td>Recruitment Target:</td>
<td>948</td>
</tr>
<tr>
<td>Recruitment as at February 2012:</td>
<td>210</td>
</tr>
<tr>
<td>Coordinating Centre:</td>
<td>Monash Medical Centre</td>
</tr>
</tbody>
</table>

**Chief Investigators:** Professor Euan M. Wallace, Joanne Mockler, Vangy Malkoutzis

**Trial Contact:** Ms. Joanne Mockler

**Contact Details:**
Ritchie Centre  
Department of Obstetrics and Gynaecology  
Monash University and Southern Health  
Monash Medical Centre  
246 Clayton Road  
Clayton Vic 3168

Tel: +61 3 9594 5458  
Fax: +61 3 9594 6389

**Trial Email:**  
joanne.mockler@med.monash.edu.au
A randomised controlled trial to determine whether continuity of care increases the rate of attempted vaginal birth after caesarean (VBAC)

ACTRN12611001214921

**Trial Question:** Would continuity of midwifery care increase the rate of attempted vaginal birth for women with a previous caesarean section?

<table>
<thead>
<tr>
<th><strong>Treatment Groups:</strong></th>
<th>Continuity of midwifery care vs standard care</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Trial Status:</strong></td>
<td>Not yet recruiting</td>
</tr>
<tr>
<td><strong>Single Centre</strong></td>
<td>Yes</td>
</tr>
<tr>
<td><strong>Recruitment Target:</strong></td>
<td>262</td>
</tr>
<tr>
<td><strong>Coordinating Centre:</strong></td>
<td>University of Technology Sydney</td>
</tr>
</tbody>
</table>

**Chief Investigator:** Caroline Homer

**Trial Contact:** Caroline Homer

**Contact Details:**
University of Technology Sydney
PO Box 123
Broadway NSW 2007

Tel: +61 2 9514 4834
Fax: +61 2 9514 4835

**Trial Email:**
Caroline.homer@uts.edu.au
Antenatal education for epidural anaesthesia in labour – a pilot study

ACTRN12611000710921

**Trial Question:** Is multi-media patient education technology superior to pamphlet delivery of information on the use of epidural anaesthesia?

<table>
<thead>
<tr>
<th>Treatment Groups:</th>
<th>Multimedia patient education module vs usual education regarding labour which includes a pamphlet</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Trial Status:</strong></td>
<td>Not yet recruiting</td>
</tr>
<tr>
<td><strong>Single Centre</strong></td>
<td>Yes</td>
</tr>
<tr>
<td><strong>Recruitment Target:</strong></td>
<td>200</td>
</tr>
<tr>
<td><strong>Coordinating Centre:</strong></td>
<td>Epworth Freemasons Maternity Hospital, Vic</td>
</tr>
</tbody>
</table>

**Chief Investigator:** Kate Claxton

**Trial Contact:** Kate Claxton

**Contact Details:**
Epworth Centre  
Suite 6.3, Level 6  
32 Erin Street  
Richmond VIC 3121

Tel: +61 3 9428 9944  
Fax: 61 3 9428 3444

**Trial Email:** kate@footsurgeon.com.au
**ARRIVaL**

**Title:** Artificial Rupture of membranes (ARM) versus repeat intra-vaginal prostaglandins for induction of labour: a randomised controlled trial

**Trial Question:** After commencement of induction (>37 weeks gestation) with a single dose of PGE2, does ARM or repeated dose/s of PGE2 reduce time taken to achieve a birth?

<table>
<thead>
<tr>
<th>Treatment Groups:</th>
<th>After induction commenced with a single dose of PGE2, women will be randomised to receive further dose/s of PGE2 or ARM.</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Trial Status:</strong></td>
<td>Currently recruiting</td>
</tr>
<tr>
<td>Single Centre:</td>
<td>Yes</td>
</tr>
<tr>
<td>Recruitment Target:</td>
<td>250</td>
</tr>
<tr>
<td>Recruitment as at February 2012:</td>
<td>131</td>
</tr>
<tr>
<td>Coordinating Centre:</td>
<td>Mater Mothers’ Research Centre, Mater Health Services, QLD</td>
</tr>
</tbody>
</table>

**Chief Investigator:** Dr Michael Beckmann

**Trial Contact:** Dr Michael Beckmann

**Contact Details:**
Mater Mothers’ Research Centre
Level 2 Quarter’s Building,
Annerley Rd
Woolloongabba QLD 4102

**Trial Email:** Michael.Beckmann@mater.org.au
Title: The prophylactic use of a Bakri Balloon for women undergoing caesarean section for placenta praevia – a randomised controlled trial

Trial Question: For women undergoing a caesarean birth for placenta praevia, does prophylactic use of Bakri balloon result in less blood loss and related morbidity when compared with routine intra and post-operative care?

Treatment Groups: Prophylactic placement of a Bakri balloon vs routine intra- or post-operative care.

Trial Status: Currently recruiting

Single Centre: Yes

Recruitment Target: 100

Recruitment as at February 2012: 35

Coordinating Centre: Mater Mothers’ Research Centre, Mater Health Services, QLD

Chief Investigator: Dr Michael Beckmann

Trial Contact: Dr Michael Beckmann

Contact Details: Mater Mothers’ Research Centre
Level 2 Quarter’s Building, Annerley Rd
Woolloongabba QLD 4102

Trial Email: Michael.Beckmann@mater.org.au
Title: Beating the Blues before Birth – Evaluating an antenatal depression treatment program: a randomised controlled trial

ACTRN12609000926235

Trial Question: Can an eight-session cognitive behavioural therapy program reduce antenatal depression, anxiety and increase health service uptake?

Treatment Groups: Individual cognitive behavioural therapy (8 weekly sessions) vs routine primary care. All women receive a clinical assessment with specialist psychologist, help linking with appropriate health professionals and support services, a ‘community connections’ pamphlet which encourages the use of community supports and includes a list of contacts for appropriate services and an ‘Emotional health during pregnancy and early parenthood’ booklet from beyondblue.

Trial Status: Currently recruiting

Single Centre: Yes

Recruitment Target: 100

Recruitment as at February 2012: 44

Coordinating Centre: Parent-Infant Research Institute, Austin Health

Chief Investigator: Professor Jeannette Milgrom

Trial Contact: Dr Charlene Schembri

Contact Details: Parent-Infant Research Institute
    Dept of Clinical & Health Psychology
    Heidelberg Repatriation Hospital Austin Health
    300 Waterdale Road
    Heidelberg West Vic 3081

Tel: +61 3 9496 4496
Fax: +61 3 9496 4148

Trial Email: Charlene.schembri@austin.org.au
Betadine Trial

ACTRN12611000379910

**Trial Question:** Does the use of betadine solution to wound prior to skin closure affect wound healing and or infection after caesarean section?

<table>
<thead>
<tr>
<th>Treatment Groups:</th>
<th>Betadine soak vs no betadine soak</th>
</tr>
</thead>
<tbody>
<tr>
<td>Trial Status:</td>
<td>Currently recruiting</td>
</tr>
<tr>
<td>Single Centre</td>
<td>Yes</td>
</tr>
<tr>
<td>Recruitment Target:</td>
<td>3000</td>
</tr>
<tr>
<td>Recruitment as at February 2012:</td>
<td>1600</td>
</tr>
<tr>
<td>Coordinating Centre:</td>
<td>Department of Obstetrics, Ipswich Hospital</td>
</tr>
<tr>
<td>Centres in Australia Currently Recruiting:</td>
<td>Ipswich Hospital, QLD</td>
</tr>
</tbody>
</table>

**Chief Investigator:** Assoc/Professor Kassam Mahomed

**Trial Contact:** Assoc/Professor Kassam Mahomed

**Contact Details:**
Department of Obstetrics
Ipswich Hospital
Chelmsford Avenue
Ipswich QLD 4305

Tel: +61 407034283
Fax: +61 7 3810 1598

**Trial Email:**
kassam_mahomed@health.qld.gov.au
Title: The CHIPS trial: Control of Hypertension In Pregnancy Study

ISRCTN71416914, NCT01192412

Trial Question: Does ‘less tight’ control vs ‘tight’ control of non-severe non-proteinuric maternal hypertension increase (or decrease) the likelihood of pregnancy loss or high level neonatal care for more than 48 hours?

Treatment Groups: Target diastolic 100 mmHg (‘less tight’ control) vs target diastolic 85 mmHg (‘tight’ control)

Trial Status: Currently recruiting

Multi Centre: Argentina, Australia, Canada, Chile, Colombia, Equatorial Guinea, Estonia, Hungary, Israel, Jordan, New Zealand, Poland, Netherlands, UK, USA

Additional Centres Needed: No

Recruitment Target: 1028

Recruitment as at February 2012: 696

Coordinating Centre: BC Women's Hospital and Health Centre, Vancouver, Canada

Centres in Australia Currently Recruiting: Campbelltown Hospital, NSW
Liverpool Hospital, NSW
Ipswich Hospital, QLD
Women’s & Children’s Hospital, SA
King Edward Memorial Hospital, WA

Chief Investigator: Dr Laura Ann Magee

Trial Contact: Dr Laura Ann Magee

Contact Details: BC Women's Hospital and Health Centre, Dept. of OB/GYN 4500 Oak Street Room B425A Vancouver Canada V6H 3N1

Tel: +1 604 875 2959
Fax: +1 604 875 3212

Trial Email: chips@cw.bc.ca

Sponsor Website: http://www.utoronto.ca/cmicr/chips/
**CiPS – Candida in Pregnancy Study**

**Title:** Treatment of asymptomatic candidiasis in pregnant women for prevention of preterm birth: a randomised trial.

NHMRC632532, ACTRN 12610000607077

**Trial Question:** In women with asymptomatic candidiasis early in pregnancy does treatment with clotrimazole prevent spontaneous preterm birth?

<table>
<thead>
<tr>
<th><strong>Treatment Groups:</strong></th>
<th>PROBE design (prospective, randomised, open-label, blinded end-point) with 2 arms: Six day course of clotrimazole pessaries vs usual care (screening result not revealed, no treatment, routine antenatal care)</th>
</tr>
</thead>
</table>

**Trial Status:** Currently recruiting

**Multi Centre:** Yes

**Additional Centres needed:** Yes, though must be within Sydney metropolitan area

**Recruitment Target:** Screen 19,000, enrol 3208

**Recruitment as at February 2012:** Screened 829, enrolled 162

**Coordinating Centre:** Royal North Shore Hospital

**Centres currently recruiting:** Royal North Shore Hospital, NSW Hornsby Ku-ring-gai Hospital, NSW St George Hospital, NSW

**Chief Investigators:** Professor Jonathan Morris, Professor Warwick Giles, Assoc/Professor Christine Roberts, Professor Judy Simpson, Dr George Kotsiou, Dr Jennifer Bowen, Dr Jane Hirst

**Trial Contact:** Kristen Rickard

**Contact Details:**
Clinical Trial Coordinator
Perinatal Research
Level 2, Building 52, Reserve Rd
Royal North Shore Hospital
St Leonards NSW 2065

Tel: +61 2 9926 6142
Fax: +61 2 9906 6742

**Trial Email:**
krrickar@nsccahs.health.nsw.gov.au
kristen.rickard@sydney.edu.au
Comparison of the reliability of continuous with intermittent blood pressure monitoring during Caesarean section under spinal anaesthesia

ACTRN12611000026921

**Trial Question/Aim:** To test the reliability (ability to provide a blood pressure reading every one minute) of blood pressure readings during caesarean section under spinal anaesthesia using two different methods (intermittent versus continuous monitoring).

<table>
<thead>
<tr>
<th>Treatment Groups:</th>
<th>Non-invasive intermittent blood pressure monitor worn on the left arm vs continuous non-invasive arterial pressure worn on the right hand.</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Trial Status:</strong></td>
<td>Not yet recruiting</td>
</tr>
<tr>
<td><strong>Single Centre:</strong></td>
<td>Yes</td>
</tr>
<tr>
<td><strong>Recruitment Target:</strong></td>
<td>59</td>
</tr>
<tr>
<td><strong>Coordinating Centre:</strong></td>
<td>Royal Women's Hospital, Melbourne</td>
</tr>
</tbody>
</table>

**Chief Investigators:** Thomas McCarthy

**Trial Contact:** Thomas McCarthy

**Contact Details:**
Department of Anaesthesia  
The Royal Women's Hospital  
Cnr Flemington Rd and Grattan St  
Parkville VIC 3052

Tel: +61 3 8345 2385

**Trial Email:** thomas.mccarthy@thewomens.org.au
Complementary medicine techniques for labour and birth: A mixed methods study

ACTRN12611001126909

**Trial Question:** For primiparous women, does an antenatal package of complementary medicine techniques for labour and birth, plus standard care, reduce rates of epidural use when compared with standard care alone?

<table>
<thead>
<tr>
<th>Treatment Groups:</th>
<th>6 complementary medicine techniques for labour and birth vs standard care of hospital based antenatal education classes.</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Trial Status:</strong></td>
<td>Recruitment to commence February 2012</td>
</tr>
<tr>
<td><strong>Single Centre:</strong></td>
<td>Yes</td>
</tr>
<tr>
<td><strong>Recruitment Target:</strong></td>
<td>192</td>
</tr>
<tr>
<td><strong>Coordinating Centre:</strong></td>
<td>University of Western Sydney, NSW</td>
</tr>
</tbody>
</table>

**Chief Investigator:** Kate Levett  
**PhD Supervisors:** Assoc/Professor Caroline Smith, Assoc/Professor Hannah Dahlen, Professor Alan Bensoussan

**Trial Contact:** Kate Levett

**Contact Details:**  
Kate Levett  
Centre for Complementary Medicine Research  
LG, Building 5, Campbelltown Campus  
Locked Bag 1797  
Penrith NSW 2751  

Tel: +61 2 4620 3284  
Fax: +61 2 4620 3291  

**Trial Email:**  
17164519@student.uws.edu.au
Cooling for perineal pain relief after childbirth

**Title:** Cooling for perineal pain relief after childbirth: a randomised trial

ACTRN1260700557437

**Trial Question:** What are the effects of two local cooling regimen in relieving pain from perineal trauma sustained during childbirth?

<table>
<thead>
<tr>
<th>Treatment Groups:</th>
<th>Systematic use of cooling, compression and being horizontal vs ice packs</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Trial Status:</strong></td>
<td>Not yet recruiting</td>
</tr>
<tr>
<td><strong>Single Centre:</strong></td>
<td>Yes</td>
</tr>
<tr>
<td><strong>Recruitment Target:</strong></td>
<td>800</td>
</tr>
<tr>
<td><strong>Coordinating Centre:</strong></td>
<td>University of Melbourne / Royal Women’s Hospital</td>
</tr>
</tbody>
</table>

**Chief Investigator:** Dr. Christine East

**Trial Contact:** Dr Christine East

**Contact Details:**
Dept Obstetrics and Gynaecology  
University of Melbourne / Royal Women's Hospital  
20 Flemington Rd  
Parkville VIC 3051

Tel: +61 3 8345 3700  
Fax: +61 3 8345 3702

**Trial Email:** eastc@unimelb.edu.au
Title: Diabetes & antenatal milk expressing (DAME): a randomised controlled trial

ACTRN12611000217909

Trial Question: Does antenatal expressing of colostrum for women with diabetes in pregnancy (requiring insulin) increase admission to the special care nursery (SCN) or the neonatal intensive care (NICU) compared with the infants of similar women receiving standard care?

Treatment Groups: Women allocated to the intervention will be taught how to hand express colostrum at 36 weeks gestation and encouraged to do this twice daily for approximately ten minutes until the time of admission to hospital to give birth, with expressed colostrum frozen for the baby’s use after birth vs standard care.

Trial Status: Currently recruiting

Multi Centre: Yes

Additional Centres Needed: No

Recruitment Target: 658

Coordinating Centre: Mother & Child Health Research, La Trobe University

Centres in Australia Currently Recruiting: Mercy Hospital for Women
                                        Royal Women’s Hospital

Chief Investigators: Della Forster, Susan Jacobs, Lisa Amir, Peter Davis, Sue Walker, Kerri McEgan, Gillian Opie

Associate Investigators: Susan Donath, Anita Moorhead, Cath McNamara, Rachael Ford, Amanda Alyward

Trial Contact: Dr Della Forster

Contact Details: Mother & Child Health Research
La Trobe University
324-328 Little Lonsdale St
Melbourne VIC 3000

Tel: +61 3 8341 8573
Fax: +61 3 8341 8533

Trial Email: d.forster@latrobe.edu.au
Determination of equivalent doses ($ED_{50}$) of metaraminol and phenylephrine needed to prevent hypotension during elective Caesarean section under regional anaesthesia

**Trial Question:** How do the sympathomimetic drugs metaraminol and phenylephrine compare in potency?

<table>
<thead>
<tr>
<th><strong>Treatment Groups:</strong></th>
<th>Randomised, double-blind up-down sequential allocation study of two groups, receiving either metaraminol or phenylephrine infusion</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Trial Status:</strong></td>
<td>Currently Recruiting</td>
</tr>
<tr>
<td><strong>Single Centre:</strong></td>
<td>Yes</td>
</tr>
<tr>
<td><strong>Recruitment Target:</strong></td>
<td>90</td>
</tr>
<tr>
<td><strong>Recruitment as at February 2012:</strong></td>
<td>29</td>
</tr>
<tr>
<td><strong>Coordinating Centre:</strong></td>
<td>King Edward Memorial Hospital, WA</td>
</tr>
</tbody>
</table>

**Chief Investigator:** Dr Nolan McDonnell

**Trial Contact:** Dr Nolan McDonnell

**Contact Details:**
King Edward Memorial Hospital  
374 Bagot Road  
Subiaco, Perth  
Western Australia  
Australia 6008

**Trial Email:**  
nolan.mcdonell@health.wa.gov.au
Does low level laser therapy reduce pain levels in cracked or grazed nipples in breastfeeding Western Australian women?

ACTRN1261100544976

**Trial Question:** Does low level laser therapy reduce pain levels in cracked or grazed nipples in breastfeeding Western Australian women?

<table>
<thead>
<tr>
<th>Treatment Groups:</th>
<th>Low level laser therapy vs placebo laser diode</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Trial Status:</strong></td>
<td>Not yet recruiting</td>
</tr>
<tr>
<td>Single Centre</td>
<td>Yes</td>
</tr>
<tr>
<td>Recruitment Target</td>
<td>40</td>
</tr>
<tr>
<td><strong>Coordinating Centre:</strong></td>
<td>Curtin University of Technology, WA</td>
</tr>
</tbody>
</table>

**Chief Investigator:** Laura Snowball

**Trial Contact:** Laura Snowball

**Contact Details:**
C/- Judith Thompson  
School of Physiotherapy  
Curtin University of Technology  
GPO Box U1987  
Perth WA 6845

**Tel:** 61 4 0796 1984

**Trial Email:** laura.snowball@postgrad.curtin.edu.au
Title: Does telephone peer support in the early postnatal period increase breastfeeding duration?

**Trial Question:** Does telephone peer support in the early postnatal period increase the proportion of infants who receive any breast milk at six months compared to infants of women who received standard care (46% to 56%)?

<table>
<thead>
<tr>
<th>Treatment Groups:</th>
<th>Women in the intervention group will be allocated a volunteer peer who will make regular telephone contact (with a minimum according to a prescribed protocol) in the first 12 weeks postpartum.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Trial Status:</td>
<td>Not yet recruiting</td>
</tr>
<tr>
<td>Multi Centre:</td>
<td>Yes</td>
</tr>
<tr>
<td>Additional Centres Needed:</td>
<td>No</td>
</tr>
<tr>
<td>Recruitment Target:</td>
<td>1028</td>
</tr>
<tr>
<td>Coordinating Centre:</td>
<td>Mother &amp; Child Health Research, La Trobe University</td>
</tr>
</tbody>
</table>
| Centres in Australia Currently Recruiting: | Royal Women's Hospital, VIC  
Barwon Health, VIC  
Sunshine Hospital, VIC |

**Chief Investigators:** Della Forster, Helen McLachlan, Mary-Ann Davey, Lisa Amir, Lisa Gold, Rhonda Small

**Associate Investigators:** Cindy-Lee Dennis, Anita Moorhead, Kim Layton, Helena Maher, Karalyn McDonald, Patrice Hickey, Kate Mortensen, Nanette Shone.

**Trial Contact:**  
Dr Della Forster

**Contact Details:**  
Mother & Child Health Research  
La Trobe University  
324-328 Little Lonsdale St  
Melbourne Vic 3000

Tel: +61 3 8341 8500  
Fax: +61 3 8341 8555

**Trial Email:**  
d.forster@latrobe.edu.au
Does the use of a patient information video affect maternal antenatal anxiety and post-natal maternal satisfaction after elective caesarean delivery?

ACTRN12611001207909

**Trial Question:** Does the use of a patient information video affect maternal antenatal anxiety and post-natal maternal satisfaction after elective caesarean delivery?

<table>
<thead>
<tr>
<th>Treatment Groups:</th>
<th>Patient information video prior to anaesthetic appointment vs usual care (an interview with the anaesthetist)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Trial Status:</strong></td>
<td>Not yet recruiting</td>
</tr>
<tr>
<td><strong>Single Centre</strong></td>
<td>Yes</td>
</tr>
<tr>
<td><strong>Recruitment Target:</strong></td>
<td>100</td>
</tr>
<tr>
<td><strong>Coordinating Centre:</strong></td>
<td>Royal Brisbane and Women’s Hospital, QLD</td>
</tr>
</tbody>
</table>

**Chief Investigator:** Dr Victoria Eley

**Trial Contact:** Dr Victoria Eley

**Contact Details:**
Department of Anaesthesia
Royal Brisbane & Women’s Hospital
Butterfield St
Hurston QLD 4006

Tel: +61 7 3636 17

**Trial Email:**
victoria.eley@health.qld.gov.au
Title: The Epi-No trial: Effect of intravaginal balloon device on levator trauma in mothers following childbirth

ACTRN12609000592246

Trial Question: Does the use of an intravaginal balloon device reduce the risk of major pelvic floor trauma at vaginal birth?

<table>
<thead>
<tr>
<th>Treatment Groups:</th>
<th>Intravaginal balloon device to distend pelvic floor muscle vs normal antenatal care.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Trial Status:</td>
<td>Currently recruiting</td>
</tr>
<tr>
<td>Multi Centre:</td>
<td>Yes</td>
</tr>
<tr>
<td>Additional Centres Needed:</td>
<td>Yes</td>
</tr>
<tr>
<td>Recruitment Target:</td>
<td>600</td>
</tr>
<tr>
<td>Recruitment as at February 2012:</td>
<td>480</td>
</tr>
<tr>
<td>Coordinating Centre:</td>
<td>Nepean Hospital</td>
</tr>
</tbody>
</table>
| Centres in Australia Currently Recruiting: | Nepean Hospital, NSW  
Royal Prince Alfred Hospital, NSW |

More collaborating centres needed

Chief Investigator: Professor Hans Peter Dietz

Trial Contact: Professor Hans Peter Dietz

Contact Details: Nepean Hospital  
Level 5 Spurrett Building  
Derby St  
Penrith NSW 2750

Tel: +61 2 4734 1474  
Fax: +61 2 4734 3485

Trial Email: hans.dietz@sydney.edu.au
**Title:** Effect of folic acid supplementation in pregnancy on preeclampsia-Folic Acid Clinical Trial (FACT)

**ISRCTN23781770**

**Trial Question:** Would high dose folic acid given through pregnancy prevent preeclampsia?

<table>
<thead>
<tr>
<th>Treatment Groups:</th>
<th>Folic Acid 4 mg vs placebo</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Trial Status:</strong></td>
<td>Currently recruiting</td>
</tr>
<tr>
<td><strong>Multi Centre:</strong></td>
<td>Recruitment is anticipated to occur in Canada, UK, Australia, New Zealand, Ireland, Israel and Argentina.</td>
</tr>
<tr>
<td><strong>Additional Centres Needed:</strong></td>
<td>Yes</td>
</tr>
<tr>
<td><strong>Recruitment Target:</strong></td>
<td>3656</td>
</tr>
<tr>
<td><strong>Recruitment as at February 2012:</strong></td>
<td>38</td>
</tr>
<tr>
<td><strong>Coordinating Centre:</strong></td>
<td>Ottawa Health Research Institute, Ottawa, Canada</td>
</tr>
<tr>
<td><strong>Centres in Australia Currently Recruiting:</strong></td>
<td>SA - Women's &amp; Children's Hospital, Adelaide:</td>
</tr>
</tbody>
</table>

**Chief Investigator:** Dr Mark Walker (Canada)  
Dr Shi Wu Wen

**Australian Principal Investigator:** Professor Bill Hague  
**Australian Coordinator:** Suzette Coat

**Australian Trial Contact:**  
Professor Bill Hague  
bill.hague@adelaide.edu.au  
Suzette Coat (suzette.coat@adelaide.edu.au)

**Canadian Trial contact:**  
Dr. Mark Walker  
Josee Champagne (folicacidclinicaltrial@ohri.ca)

**Contact Details:**  
Ottawa Hospital Research Institute  
Department of Obstetrics, Gynecology and Newborn Care  
OMNI Research Group  
501 Smyth Rd. Box 241  
Ottawa, Ontario K1H 8L6

**Trial Email:**  
folicacidclinicaltrial@ohri.ca

**Trial Website:**  
Under development
Fetal lactate measurement to reduce caesarean sections during labour: a randomised trial

ACTRN12611000172909

**Trial Question:** Does a lactate test in addition to standard monitoring of the fetal heart rate by cardiotocography make a difference in the number of women having caesarean births?

<table>
<thead>
<tr>
<th><strong>Treatment Groups:</strong></th>
<th>Addition of fetal blood sampling for lactate measurement during labour and monitoring of fetal heart rate by cardiotocography vs standard monitoring of fetal heart rate by cardiotocography only</th>
</tr>
</thead>
</table>

**Trial Status:** Recruiting to commence 2012

**Single Centre** Yes

**Recruitment Target:** 600

**Coordinating Centre:** Royal Women’s Hospital, VIC

---

**Chief Investigator:** Dr Christine East

**Trial Contact:** Dr Christine East

**Contact Details:**
Royal Women’s Hospital  
20 Flemington Road  
Parkville Vic 3052

Tel: +61 3 8345 3700  
Fax: +61 3 8345 3702

**Trial Email:** eastc@unimelb.edu.au
Fetal Middle Cerebral Artery (MCA) Doppler to time second and subsequent transfusions for women with red cell alloimmunisation: a randomised trial

ACTRN12608000643370

**Trial Question:** To assess whether (MCA) Doppler can be safely used to determine the timing of second and subsequent fetal blood transfusions without increasing the risk of adverse fetal and neonatal health outcomes.

<table>
<thead>
<tr>
<th><strong>Treatment Groups:</strong></th>
<th>Middle Cerebral Artery (MCA) vs standard nomogram</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Trial Status:</strong></td>
<td>Currently recruiting</td>
</tr>
<tr>
<td><strong>Multi Centre:</strong></td>
<td>Canada, Australia, United Kingdom, USA, Europe, United Arab States</td>
</tr>
<tr>
<td><strong>Additional Centres Needed:</strong></td>
<td>Yes</td>
</tr>
<tr>
<td><strong>Recruitment Target:</strong></td>
<td>564</td>
</tr>
<tr>
<td><strong>Recruitment as at February 2012:</strong></td>
<td>41</td>
</tr>
<tr>
<td><strong>Coordinating Centre:</strong></td>
<td>The University of Adelaide, SA</td>
</tr>
</tbody>
</table>

**Centres in Australia Currently Recruiting:**
- ACT – The Canberra Hospital
- NSW – Royal Prince Alfred Hospital
- QLD – Mater Mothers’ Hospital
- Royal Brisbane Women’s Hospital
- SA – Women’s & Children’s Hospital
- WA – King Edward Memorial Hospital
- NZ – Auckland Hospital
- Wellington Women’s Hospital

**Steering Committee:** Professor Jodie Dodd, A/Professor Jan Dickinson, Dr Chad Andersen, Dr Greg Ryan, Dr Rory Windrim.

**Trial Contact:** Professor Jodie Dodd

**Contact Details:**
ARCH, The Robinson Institute
Discipline of Obstetrics & Gynaecology
The University of Adelaide
Women’s & Children’s Hospital
72 King William Road
North Adelaide SA 5006

Tel: +61 8 8161 7657
Fax: +61 8 8161 7652

More collaborating centres needed
Help-seeking for postnatal depression as a major public health problem: A cluster randomised controlled trial of motivational interviewing

ACTRN12611000635965

**Trial Question:** Would a brief motivational interviewing intervention delivered in the context of a routine postnatal screening and emotional health assessment improve access to treatment for women who experience postnatal depression?

<table>
<thead>
<tr>
<th>Treatment Groups:</th>
<th>Motivational interviewing intervention by MCH nurses vs standard care, MCH nurses follow usual practice when talking with mothers</th>
</tr>
</thead>
<tbody>
<tr>
<td>Trial Status:</td>
<td>Currently recruiting</td>
</tr>
<tr>
<td>Single Centre</td>
<td>Yes</td>
</tr>
<tr>
<td>Recruitment Target:</td>
<td>800</td>
</tr>
<tr>
<td>Recruitment as at February 2012:</td>
<td>144</td>
</tr>
<tr>
<td>Coordinating Centre:</td>
<td>Parent-Infant Research Institute, VIC</td>
</tr>
</tbody>
</table>

**Chief Investigator:** Dr Charlene Schembri

**Trial Contact:** Dr Charlene Schembri

**Contact Details:**
Parent-Infant Research Institute  
Heidelberg Repatriation Hospital  
300 Waterdale Rd  
Heidelberg Heights VIC 3081

Tel: +61 3 9496 4496  
Fax: +61 3 9496 4148

**Trial Email:** charlene.schembri@austin.org.au
**HIPP Study**

Health In Pregnancy and Post Birth: The HIPP Study

**ACTRN12611000331932**

**Trial Question:** Is a specialised health coaching intervention during pregnancy more successful than education alone, in preventing excessive gestational weight gain and postpartum weight retention 12 months post birth?

<table>
<thead>
<tr>
<th>Treatment Groups:</th>
<th>Specialised health coaching and education vs education alone</th>
</tr>
</thead>
<tbody>
<tr>
<td>Trial Status:</td>
<td>Currently recruiting</td>
</tr>
<tr>
<td>Single Centre</td>
<td>Yes</td>
</tr>
<tr>
<td>Recruitment Target:</td>
<td>220</td>
</tr>
<tr>
<td>Recruitment as at February 2012:</td>
<td>28</td>
</tr>
<tr>
<td>Coordinating Centre:</td>
<td>Deakin University</td>
</tr>
</tbody>
</table>

**Chief Investigator:** Assoc/Professor Helen Skouteris

**Trial Contact:** Assoc/Professor Helen Skouteris

**Contact Details:**
School of Psychology  
Deakin University  
221 Burwood Highway  
Burwood VIC 3125

Tel: +61 3 9251 7699  
Fax: +61 3 9244 6858

**Trial Email:** helen.skouteris@deakin.edu.au
ICARIS

Title: Impact of caesarean rates following injections of sterile water: a randomised controlled trial
ACTRN12611000221954

Trial Question: Do sterile water injections reduce the rate of caesarean section for women in labour?

<table>
<thead>
<tr>
<th>Treatment Groups:</th>
<th>Sterile water injections and standard care to women with back pain in first stage of labour vs placebo and standard care</th>
</tr>
</thead>
<tbody>
<tr>
<td>Trial Status:</td>
<td>Not yet recruiting</td>
</tr>
<tr>
<td>Multi Centre:</td>
<td>Yes</td>
</tr>
<tr>
<td>Additional Centres Needed:</td>
<td></td>
</tr>
<tr>
<td>Recruitment Target:</td>
<td>1846</td>
</tr>
<tr>
<td>Coordinating Centre:</td>
<td>Mater Health Services</td>
</tr>
</tbody>
</table>
| Centres in Australia that will be recruiting: | Ipswich Hospital  
Mater Mothers' Hospital  
Royal Brisbane and Women's Hospital  
Townsville Hospital |

Chief Investigator: Mr Nigel Lee

Trial Contact: Mr Nigel Lee

Contact Details:
Mater Mothers’ Research Centre  
Level 2 Quarter’s Building  
Annerley Rd  
Woolloongabba QLD 4102

Trial Email:  
Nigel.Lee@mater.org.au
IDEAL

Title: Investigation of dietary advice and lifestyle for women with borderline gestational diabetes

ACTRN12607000174482

Trial Question: Does the use of dietary and lifestyle advice for women with borderline gestational diabetes reduce the risk of infant morbidity and maternal morbidity?

<table>
<thead>
<tr>
<th>Treatment Groups:</th>
<th>Individualised advice regarding diet and lifestyle vs routine care for women with borderline gestational diabetes</th>
</tr>
</thead>
<tbody>
<tr>
<td>Trial Status:</td>
<td>Currently recruiting</td>
</tr>
<tr>
<td>Multi Centre:</td>
<td>Yes</td>
</tr>
<tr>
<td>Additional Centres Needed:</td>
<td>No</td>
</tr>
<tr>
<td>Recruitment Target:</td>
<td>682</td>
</tr>
<tr>
<td>Recruitment as at February 2012:</td>
<td>577</td>
</tr>
<tr>
<td>Coordinating Centre:</td>
<td>Australian Research Centre for Health of Women and Babies (ARCH), The University of Adelaide</td>
</tr>
</tbody>
</table>

Centres in Australia Currently Recruiting:

- **NSW** – Nepean Hospital
- **QLD** – Townsville Hospital
- Caboolture Hospital
- Redcliffe Hospital
- Ipswich Hospital
- **SA** – Women’s & Children’s Hospital,
  Flinders Medical Centre,
  Lyell McEwin Hospital.
- **TAS** – Launceston Hospital.
- **VIC** – The Royal Women’s Hospital

Steering Committee:
Professor Caroline Crowther, Professor Bill Hague, Philippa Middleton, Dr Peter Baghurst, Emeritus Professor Jeffrey Robinson

Trial Contact:
Professor Caroline Crowther

Trial Coordinator:
Ms Pat Ashwood

Contact Details:
Australian Research Centre for Health of Women and Babies, The Robinson Institute
Discipline of Obstetrics & Gynaecology
The University of Adelaide
Women's & Children's Hospital
72 King William Road
North Adelaide SA 5006

Tel: +61 8 8161 7767
Fax: +61 8 8161 7652

Trial Email:
ideal@adelaide.edu.au
Title: A randomised clinical trial of different infusion rates of magnesium sulphate before preterm birth for neuroprotection.

ACTRN012605000765628

Trial Question: Will a slower loading infusion rate of prenatal magnesium sulphate as compared with the current standard infusion rate reduce maternal adverse effects?

<table>
<thead>
<tr>
<th>Treatment Groups:</th>
<th>20 minute loading dose (4 g over 20 minutes) vs 60 minute loading dose (4 g over 60 minutes)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Trial Status:</td>
<td>Currently recruiting</td>
</tr>
<tr>
<td>Single Centre</td>
<td>Yes</td>
</tr>
<tr>
<td>Recruitment Target:</td>
<td>51</td>
</tr>
<tr>
<td>Recruitment as at February 2012:</td>
<td>42</td>
</tr>
<tr>
<td>Coordinating Centre</td>
<td>Women's &amp; Children's Hospital, Adelaide</td>
</tr>
</tbody>
</table>

Chief Investigator: Professor Caroline Crowther

Trial Contact: Professor Caroline Crowther

Contact Details: ARCH (Australian Research Centre for Health of Women and Babies)  
Discipline of Obstetrics & Gynaecology  
The University of Adelaide  
Women's & Children's Hospital  
72 King William Road  
North Adelaide SA 5006

Tel: +61 8 8161 7767  
Fax: +61 8 8161 7652

Trial Email: emily.bain@adelaide.edu.au
**MAGENTA**

**Magnesium sulphate at 30 to 34 weeks’ Gestational Age: Neuroprotection Trial**

ACTRN12611000491965

**Trial Question:** Does antenatal magnesium sulphate given to women at risk of imminent preterm birth between 30 and 34 weeks' gestation reduce the risk of death or cerebral palsy in their children?

<table>
<thead>
<tr>
<th>Treatment Groups:</th>
<th>4 g of magnesium sulphate diluted in 100 mL of normal saline administered as an IV infusion over 30 minutes vs saline placebo</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Trial Status:</strong></td>
<td>Currently recruiting</td>
</tr>
<tr>
<td><strong>Multi Centre</strong></td>
<td>Australia &amp; New Zealand</td>
</tr>
<tr>
<td><strong>Additional Centres Needed</strong></td>
<td>Yes</td>
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<td><strong>Recruitment Target:</strong></td>
<td>1676</td>
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<tr>
<td><strong>Recruitment as at February 2012:</strong></td>
<td>2</td>
</tr>
<tr>
<td><strong>Coordinating Centre:</strong></td>
<td>Australian Research Centre for Health of Women and Babies (ARCH), The University of Adelaide</td>
</tr>
</tbody>
</table>

**Collaborating Centres:**
- **SA** – Women’s & Children's Hospital, Flinders Medical Centre.
- **NSW** – Royal North Shore Hospital, St George Hospital.
- **QLD** – Mater Mother’s Hospital, Royal Brisbane & Women’s Hospital, Townsville Hospital, Ipswich Hospital.
- **VIC** – Royal Women’s Hospital, Mercy Hospital for Women, Monash Medical Centre.
- **TAS** – Royal Hobart Hospital.
- **New Zealand** – Auckland City Hospital, Waikato Hospital, Christchurch Hospital, Middlemore Hospital.

**Chief Investigators:** Professor Caroline Crowther, Philippa Middleton, Assoc/Professor Dominic Wilkinson, Assoc/Professor Ross Haslam

**Trial Contact:** Professor Caroline Crowther

**Trial Coordinator:** Ms Pat Ashwood

**Contact Details:**
Australian Research Centre for Health of Women and Babies, The Robinson Institute
The University of Adelaide
Women's & Children’s Hospital
72 King William Road
North Adelaide SA 5006

Tel: +61 8 8161 7767
Fax: +61 8 8161 7652

**Trial Email:** magenta@adelaide.edu.au
**Title:** Metformin for the Prevention of Gestational Diabetes

**ACTRN12610000157077**

**Trial Question:** Would giving metformin from the second trimester of pregnancy to women who had had previous gestational diabetes, prevent them from developing recurrent gestational diabetes?

<table>
<thead>
<tr>
<th>Treatment Groups:</th>
<th>Metformin vs placebo</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Trial Status:</strong></td>
<td>Currently recruiting</td>
</tr>
<tr>
<td><strong>Multi Centre:</strong></td>
<td>Two sites in South Australia</td>
</tr>
<tr>
<td><strong>Additional Centres Needed:</strong></td>
<td>No</td>
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<tr>
<td><strong>Recruitment Target:</strong></td>
<td>266</td>
</tr>
<tr>
<td><strong>Recruitment as at February 2012:</strong></td>
<td>6</td>
</tr>
<tr>
<td><strong>Coordinating Centre:</strong></td>
<td>Women's and Children's Hospital, Children's Youth and Women's Health Service, North Adelaide</td>
</tr>
<tr>
<td><strong>Centres in Australia Currently Recruiting:</strong></td>
<td>Women's and Children's Hospital</td>
</tr>
</tbody>
</table>

**Chief Investigators:** Professor Bill Hague

**Trial Contact:** Shalini Nilajgi, Suzette Coat

**Contact Details:**
Discipline of Obstetrics & Gynaecology
The University of Adelaide
Women's & Children's Hospital
72 King William Road
North Adelaide SA 5006

**Trial Email:**
bill.hague@adelaide.edu.au
shalini.nilajgi@adelaide.edu.au
suzette.coat@adelaide.edu.au
Online cognitive behaviour therapy (MoodGYM) for the prevention of postnatal depression in at-risk mothers: a randomised controlled trial

**ACTRN12609001032246**

**Trial Questions:** Is the MoodGYM program acceptable and effective for preventing depression in at-risk women in the postnatal period?

<table>
<thead>
<tr>
<th><strong>Treatment Groups:</strong></th>
<th>MoodGYM online program vs Health watch website emails directing women to modules containing general wellbeing information only</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Trial Status:</strong></td>
<td>Not yet recruiting</td>
</tr>
<tr>
<td><strong>Single Centre</strong></td>
<td>Yes</td>
</tr>
<tr>
<td><strong>Recruitment Target:</strong></td>
<td>175</td>
</tr>
<tr>
<td><strong>Coordinating Centre:</strong></td>
<td>Centre for Mental Health Research, The Australian National University</td>
</tr>
</tbody>
</table>

**Chief Investigator:** Bethany Jones

**Trial Contact:** Bethany Jones

**Contact Details:**
The Australian National University  
Building 63  
Eggleston Road  
Canberra ACT 0200  
Tel: +61 433 167 919

**Trial Email:** bethany.jones@anu.edu.au
Outpatient Foley catheter vs inpatient Prostin gel for induction of labour

ACTRN12609000374268

**Trial Question:** Aims to compare clinical effectiveness, patient acceptability and safety of the outpatient use of Foley catheter, in women requiring cervical ripening as part of induction of labour.

<table>
<thead>
<tr>
<th>Treatment Groups:</th>
<th>Foley catheter in outpatient setting vs intravaginal PGE2 gel in inpatient setting</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Trial Status:</strong></td>
<td>Currently recruiting</td>
</tr>
<tr>
<td><strong>Single Centre</strong></td>
<td>Yes</td>
</tr>
<tr>
<td><strong>Recruitment Target:</strong></td>
<td>200</td>
</tr>
<tr>
<td><strong>Recruitment as at February 2012:</strong></td>
<td>26</td>
</tr>
<tr>
<td><strong>Coordinating Centre:</strong></td>
<td>Royal Hospital for Women, NSW</td>
</tr>
</tbody>
</table>

**Chief Investigator:** Dr Amanda Henry

**Trial Contact:** Dr Amanda Henry

**Contact Details:**
Department of Materno-fetal Medicine  
Royal Hospital for Women  
Barker Street  
Randwick NSW 2031

Tel: +61 2 9382 6052  
Fax: +61 2 9382 6706

**Trial Email**
amanda.henry@sesiahs.health.nsw.gov.au
Oxytocin as an adjunct to interaction coaching and baby massage to improve bonding in early postpartum

ACTRN12609000483257

**Trial Question:** To assess any additional effects of oxytocins delivered alongside interaction coaching and massage in improve maternal behaviour towards the infant.

<table>
<thead>
<tr>
<th><strong>Treatment Groups:</strong></th>
<th>Mothers receive oxytocin via nasal spray vs placebo</th>
</tr>
</thead>
</table>

**Trial Status:** Currently recruiting

**Single Centre** Yes

**Recruitment Target:** 100

**Recruitment as at February 2012:**

**Coordinating Centre:** The University of New South Wales

**Chief Investigator:** Rebecca McErlean

**Trial Contact:** Rebecca McErlean

**Contact Details:**
School of Psychology  
University of New South Wales  
Kensington NSW 2052

Tel: +61 2 9385 3828

**Trial Email**
rmcerlean@psy.unsw.edu.au
Piloting a Midwife Initiated Oral Health-Dental Service (MIOH-DS) to improve the oral health of pregnant women

ACTRN12610000794000

**Trial Question:**

1. How effective is a MIOH-DS intervention involving oral health education, assessment and referral to dental services in improving women’s uptake of dental services, oral health status and knowledge?
2. Are midwives able to identify pregnant women at risk of poor oral health using the oral health screening tool?: What is the sensitivity and specificity of the oral health screening tool administered by midwives in predicting pregnant women at risk of poor oral health?
3. What is the impact of the MIOH-DS intervention on the incidence of preterm birth, and low birth weight infants? (We acknowledge that there is still debate regarding the effectiveness of dental treatment on pregnancy outcomes, however we believe testing the impact of this service will provide meaningful information in this research area)

**Treatment Groups:**

| Treatment Groups: | Midwifery intervention involving oral health education, assessment and referrals to current dental services (private, public or health fund clinics) vs midwifery intervention as above and dental intervention involving prompt treatment at specific public dental clinics (through a voucher) vs no midwifery or dental intervention (current practice). |

**Trial Status:**

Currently recruiting

**Single Centre**

Yes

**Recruitment Target:**

390

**Recruitment as at February 2012:**

300

**Coordinating Centre:**

Centre for Applied Nursing Research, South Western Sydney Local Health District/ University of Western Sydney, NSW

**Chief Investigator:** Dr Ajesh George

**Trial Contact:** Dr Ajesh George

**Contact Details:**

Centre for Applied Nursing Research
Locked Bag 1871
Liverpool BC NSW 1871

Tel: +61 2 9612 0672

**Trial Email:**

ajesh.george@sswhs.nsw.gov.au
Title: Percutaneous Shunting for lower-urinary tract obstruction

ISRCTN53328556

Trial Question: Does intrauterine vesico-amniotic shunting for fetal bladder outflow obstruction, care improve prenatal and perinatal mortality and renal function compared with conservative, non-interventional care

<table>
<thead>
<tr>
<th>Treatment Groups:</th>
<th>Fetal vesico-amniotic shunt vs no shunt</th>
</tr>
</thead>
<tbody>
<tr>
<td>Trial Status:</td>
<td>Currently recruiting</td>
</tr>
<tr>
<td>Multi Centre:</td>
<td>18 centres across UK. 3 centres internationally – Adelaide, Hong Kong, Dublin</td>
</tr>
<tr>
<td>Additional Centres Needed:</td>
<td>Yes</td>
</tr>
<tr>
<td>Recruitment Target:</td>
<td>200</td>
</tr>
<tr>
<td>Recruitment as at February 2012:</td>
<td>24</td>
</tr>
<tr>
<td>Trial Office:</td>
<td>The Clinical Trials Unit, University of Birmingham</td>
</tr>
<tr>
<td>Australian Collaborating Centre:</td>
<td>Women’s and Children’s Hospital, Adelaide, South Australia</td>
</tr>
</tbody>
</table>

Local Investigators:
WCH: Dr Chris Wilkinson, Dr Peter Muller, Professor Jodie Dodd, Professor Caroline Crowther

Trial Coordinator: Ms Pamela Adelson

Trial Contact: Professor Mark Kilby

Contact Details:
University of Birmingham
Department of Fetal Medicine
Birmingham Women’s Hospital
Metchley Park Road
Birmingham B15 2TG
United Kingdom

Tel: +44 (0)121 627 2775
Fax: +44 (0) 121 415 4837

Trial Email: m.d.kilby@bham.ac.uk

Trial Website: http://www.pluto.bham.ac.uk
**PO- PROM Trial**

Prostaglandin Gel Versus Oxytocin for Induction Of Labour In Term Prelabour Rupture Of Membranes

ACTRN12612000093886

**Trial Question:** Is vaginal prostaglandin compared to oxytocin a safe and effective method of induction of labour in women with PROM at term?

<table>
<thead>
<tr>
<th><strong>Treatment Groups:</strong></th>
<th>Vaginal PGF2 alpha vs oxytocin infusion</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Trial Status:</strong></td>
<td>Currently recruiting</td>
</tr>
<tr>
<td><strong>Single Centre:</strong></td>
<td>Yes</td>
</tr>
<tr>
<td><strong>Recruitment Target:</strong></td>
<td>300</td>
</tr>
<tr>
<td><strong>Recruitment as at February 2012:</strong></td>
<td>115</td>
</tr>
<tr>
<td><strong>Coordinating Centre:</strong></td>
<td>Department of Obstetrics, Ipswich Hospital</td>
</tr>
<tr>
<td><strong>Centres in Australia Currently Recruiting:</strong></td>
<td>Ipswich Hospital, QLD</td>
</tr>
</tbody>
</table>

**Chief Investigator:** Assoc/Prof Kassam Mahomed and Dr Chris Weekes

**Trial Contact:** Assoc/Prof Kassam Mahomed

**Contact Details:**
Department of Obstetrics
Ipswich Hospital
Chelmsford Avenue
Ipswich QLD 4305

Tel: +61 407034283
Fax +61 7 3810 1598

**Trial Email:** kassam_mahomed@health.qld.gov.au
PMTrial

Pregnancy Maintenance Trial

ACTRN12611000401954

**Trial Question:** In pregnant women with previous subfertility, does progesterone supplementation decrease the likelihood of miscarriage?

<table>
<thead>
<tr>
<th>Treatment Groups:</th>
<th>Progesterone pessary 400 mg vs placebo pessary</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Trial Status:</strong></td>
<td>Currently recruiting</td>
</tr>
<tr>
<td><strong>Single Centre</strong></td>
<td>Yes</td>
</tr>
<tr>
<td><strong>Recruitment Target:</strong></td>
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<tr>
<td><strong>Recruitment as at February 2012:</strong></td>
<td>3</td>
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<tr>
<td><strong>Coordinating Centre:</strong></td>
<td>Mater Mothers’ Hospital QLD</td>
</tr>
</tbody>
</table>

**Chief Investigator:** - Dr Luke McLindon

**Trial Contact:** - Chris Riley

**Contact Details:**
Fertility Assessment and Research Clinic
Mater Mothers’ Hospital
Raymond Terrace
South Brisbane QLD 4101

Tel: +61 7 3163 8437
Fax: +61 7 3163 2137

**Trial Email:**
Naturalfertility@mater.org.au
Title: Post partum risk of hypertension after non-steroidal analgesic use (excluding paracetamol)

Trial Question: Do newly used anti-inflammatory drugs used for postpartum pain relief have an adverse effect on maternal blood pressure?

<table>
<thead>
<tr>
<th>Treatment Groups:</th>
<th>Non-steroidal treatment vs placebo</th>
</tr>
</thead>
<tbody>
<tr>
<td>Trial Status:</td>
<td>Currently recruiting</td>
</tr>
<tr>
<td>Single Centre</td>
<td></td>
</tr>
<tr>
<td>Recruitment Target:</td>
<td>284</td>
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<td>Recruitment as at February 2012:</td>
<td>200</td>
</tr>
</tbody>
</table>
| Coordinating Centre: | Royal Prince Alfred Hospital, NSW  
Campbelltown Hospital, NSW |

Steering Committee: Professor Annemarie Hennessy

Trial Coordinator: Professor Annemarie Hennessy

Trial Contact: Professor Annemarie Hennessy

Contact Details: University of Western Sydney  
Campbelltown NSW 2560

Tel: +61 2 9852 4672
**Title:** Immediate delivery vs expectant care in women with preterm prelabour rupture of the membranes close to term – A randomised clinical trial

**ISRCTN44485060**

**Trial Question:** Does early planned delivery of women with PPROM close to term result in less neonatal and maternal morbidity and fewer economic costs compared with expectant management?

**Treatment Groups:**
- Immediate delivery (within 24 hours) vs expectant management

**Trial Status:**
- Currently recruiting

**Multi Centre:**
- Australia, NZ, UK, South Africa, Brazil, Argentina, Egypt, Poland, Romania, Norway, Uruguay

**Additional Centres Needed:**
- No

**Recruitment Target:**
- 1812

**Recruitment as at February 2012:**
- 1288

**Coordinating Centre:**
- Dept of Obstetrics & Gynaecology, Royal North Shore Hospital

**Centres Currently Recruiting:**
- ACT - The Canberra Hospital
- **NSW** - Royal North Shore Hospital;
- Nepean Hospital;
- RPA Women’s & Babies Hospital;
- Westmead Hospital;
- Hornsby Ku-ring-gai Hospital;
- St George Hospital;
- Wollongong Hospital;
- John Hunter Hospital;
- Liverpool Hospital;
- Gosford Hospital;
- Royal Hospital for Women;
- Campbeltown Hospital;
- **SA** - Women’s & Children’s Hospital;
- **QLD** – Ipswich Hospital;
- Royal Brisbane Women’s Hospital;
- Mater Mothers’ Hospital;
- Redcliffe Hospital;
- Caboolture Hospital;
- The Townsville Hospital;
- Gold Coast Hospital;
- **VIC** - Royal Women’s Hospital;
- Monash Medical Centre;
- **TAS** - Launceston Hospital;
- North Western Regional Hospital;
- **WA** - King Edward Memorial Hospital;
- **NZ** - Middlemore Hospital;
- Palmerston North Hospital;
- Dunedin Hospital;
- Christchurch Women’s Hospital
- Auckland City Hospital

**Coordinating Committee:**
Professor Jonathan Morris, Assoc/Professor Christine Roberts, Professor Caroline Crowther, Professor David Henderson-Smart

**Trial Contact:** Professor Jonathan Morris
- **Contact Details:**
  - Dept Obstetrics & Gynaecology University of Sydney
  - Level 2, Building 52
  - Royal North Shore Hospital
  - St Leonards NSW 2065
  - Tel: +61 2 9926 7861
  - Fax: +61 2 9906 6742

**Trial Coordinator:** Ms Diana Bond
- **Trial Website:** [http://www.wombatcollaboration.net/doc/InfoSheet_PPROMT_0307.pdf](http://www.wombatcollaboration.net/doc/InfoSheet_PPROMT_0307.pdf)
- **Trial Email:** ppromt@med.usyd.edu.au
Title: Pregnancy and Glycaemic Index Outcomes Study comparing a low glycaemic index (GI) diet to a standard healthy diet.

ACTRN12610000174088

Trial Question: What effect does a low GI diet have on birth weight, development of gestational diabetes and child obesity compared with a standard healthy diet?

<table>
<thead>
<tr>
<th>Treatment Groups:</th>
<th>Low GI dietary advice from a dietitian vs general healthy eating advice from a dietitian</th>
</tr>
</thead>
<tbody>
<tr>
<td>Trial Status:</td>
<td>Currently recruiting</td>
</tr>
<tr>
<td>Single Centre</td>
<td>Yes</td>
</tr>
<tr>
<td>Recruitment Target:</td>
<td>700</td>
</tr>
<tr>
<td>Recruitment as at February 2012:</td>
<td>550</td>
</tr>
<tr>
<td>Coordinating Centre:</td>
<td>University of Wollongong, NSW</td>
</tr>
</tbody>
</table>

Chief Investigator: Professor Robert Moses

Trial Contact: Professor Robert Moses

Contact Details: Clinical Trials and Research Unit
Diabetes Centre
Level 2, 304 Crown Street
Wollongong NSW 2500

Trial Email: Robert.Moses@sesiahs.health.nsw.gov.au
Preventing diabetes in pregnancy from progressing to type 2 diabetes

**Title:** The effect of a group behaviour intervention program on preventing diabetes pregnancy from progressing to type 2 diabetes: macrolevel system change in South Australia and Victoria.

ACTRN12610000338066

**Trial Question:** Would a lifestyle modification program prevent women who have had GDM progress to type 2 diabetes?

<table>
<thead>
<tr>
<th>Treatment Groups:</th>
<th>Group behaviour intervention program vs usual care, for 12 months after giving birth</th>
</tr>
</thead>
<tbody>
<tr>
<td>Trial Status:</td>
<td>Currently recruiting</td>
</tr>
<tr>
<td>Multi Centre</td>
<td>Yes</td>
</tr>
<tr>
<td>Recruitment Target:</td>
<td>574</td>
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<tr>
<td>Recruitment as at February 2012:</td>
<td>20</td>
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<tr>
<td>Coordinating Centre:</td>
<td>Greater Green Triangle University Department of Rural Health, Flinders and Deakin Universities.</td>
</tr>
</tbody>
</table>

**Chief Investigator:** Professor James Dunbar

**Trial Contact:** Professor James Dunbar

**Contact Details:**
Greater Green Triangle University  
Department of Rural Health  
Flinders and Deakin Universities  
Warrnambool, VIC 3280

Tel: +61 3 5563 3504  
Fax: +61 3 5563 3144

**Trial Email:** Director@greaterhealth.org
Probiotics for the prevention of gestational diabetes in overweight and obese women

ACTRN12611001208998

**Trial Question:** Do probiotics commencing at 16 weeks gestation reduce rates of gestational diabetes in pregnancy in overweight and obese women?

<table>
<thead>
<tr>
<th>Treatment Groups:</th>
<th>Lactobacillus rhamnosus GG and bifidobacterium lactis BB12 capsules vs placebo</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Trial Status:</strong></td>
<td>Not yet recruiting</td>
</tr>
<tr>
<td><strong>Single Centre</strong></td>
<td>Yes</td>
</tr>
<tr>
<td><strong>Recruitment Target:</strong></td>
<td>640</td>
</tr>
<tr>
<td><strong>Coordinating Centre:</strong></td>
<td>Royal Brisbane and Women's Hospital, QLD</td>
</tr>
</tbody>
</table>

**Chief Investigator:** Assoc/Professor Leone Callaway

**Trial Contact:** Assoc/Professor Leone Callaway

Contact Details:
Royal Brisbane and Women's Hospital
Level 9, Health Sciences Building
Butterfield Street
Herston QLD 4029

Tel: +61 73346 5273

**Trial Email:** l.callaway@uq.edu.au
**Title:** Progesterone after previous preterm birth for the prevention of neonatal respiratory distress syndrome

**ISRCTN20269066; NHMRC207744; NCT00097110**

**Trial Question:** Does vaginal progesterone therapy in women with a previous spontaneous preterm birth reduce the risk of neonatal respiratory distress syndrome in the subsequent pregnancy?

**Treatment Groups:**
Vaginal progesterone pessaries vs vaginal placebo pessaries.

**Trial Status:**
Currently recruiting

**Multi Centre:**
Australia, New Zealand, Canada

**Recruitment Target:**
784

**Recruitment as at February 2012:**
745

**Steering Committee:**
Professor Caroline Crowther, Professor Jodie Dodd, Dr Andrew McPhee, Assoc/Professor Vicky Flenady, Emeritus Professor Jeffrey Robinson

**Centres Currently Recruiting:**

In Australia and New Zealand
- NSW – St George Hospital;
- Nepean Hospital;
- Royal North Shore Hospital;
- Liverpool Hospital;
- Westmead Hospital;
- Royal Hospital for Women.
- QLD - Ipswich Hospital;
- Logan Hospital;
- Mater Mothers’ Hospital;
- Redcliffe Hospital;
- Caboolture Hospital;
- The Townsville Hospital;
- Mater Hospital Mackay.
- ACT - The Canberra Hospital.

In New Zealand
- NZ - Christchurch Women’s Hospital
- Wellington Women’s Hospital;
- Auckland City Hospital;
- Waikato Hospital;

In Canada
- Canada – Mt Sinai, Toronto.

**Trial Coordinator:**
Ms Pat Ashwood

**Contact Details:**
ARCH
Discipline of Obstetrics & Gynaecology
The University of Adelaide
Women’s & Children’s Hospital
72 King William Road
North Adelaide SA 5006

Tel: +61 8 8161 7767
Fax: +61 8 8161 7652

**Trial Website:**

**Trial Email:**
progress@adelaide.edu.au
STOP Trial
Supporting Threatened Outcomes with Progesterone

ACTRN12611000405910

**Trial Question:** Does using progesterone in women with threatened miscarriage increase the chance of a live baby?

<table>
<thead>
<tr>
<th>Treatment Groups:</th>
<th>Progesterone pessary 400 mg nightly vs placebo pessary</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Trial Status:</strong></td>
<td>Currently recruiting</td>
</tr>
<tr>
<td><strong>Single Centre</strong></td>
<td>Yes</td>
</tr>
<tr>
<td><strong>Recruitment Target:</strong></td>
<td>386</td>
</tr>
<tr>
<td><strong>Recruitment as at February 2012:</strong></td>
<td>2</td>
</tr>
<tr>
<td><strong>Coordinating Centre:</strong></td>
<td>Mater Mothers’ Hospital</td>
</tr>
</tbody>
</table>

**Chief Investigator:** Dr Luke McLindon

**Trial Contact:** Chris Riley

**Contact Details:**
Fertility Assessment and Research Clinic
Mater Mothers’ Hospital
Raymond Terrace
South Brisbane QLD 4101

Tel: +61 7 3163 8111

**Trial Email:**
naturalfertility@mater.org.au
**Title:** A randomised, controlled trial of a single versus a four intradermal sterile water injection technique for relief of continuous lower back pain during labour.

**Trial Question:** Is administration of the single needle sterile water injection technique no worse (or non-inferior) to the usual 4 injection sterile water injection method in reducing continuous lower back pain experienced during labour?

<table>
<thead>
<tr>
<th>Treatment Groups:</th>
<th>4 needle vs single sterile water injection method.</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Trial Status:</strong></td>
<td>Currently recruiting</td>
</tr>
<tr>
<td><strong>Multi Centre:</strong></td>
<td>Yes</td>
</tr>
<tr>
<td><strong>Recruitment Target:</strong></td>
<td>319</td>
</tr>
<tr>
<td><strong>Recruitment as at February 2012:</strong></td>
<td>39</td>
</tr>
<tr>
<td><strong>Coordinating Centre:</strong></td>
<td>Mater Mothers’ Research Centre, Mater Health Services</td>
</tr>
<tr>
<td><strong>Centres in Australia Currently Recruiting:</strong></td>
<td>Mater Mothers’ Hospital, QLD</td>
</tr>
<tr>
<td></td>
<td>Royal Brisbane and Women’s Hospital, QLD</td>
</tr>
</tbody>
</table>

**Chief Investigator:** Mr Nigel Lee

**Trial Contact:** Mr Nigel Lee

**Contact Details:** Mater Mothers’ Research Centre
Level 2 Quarter’s Building,
Annerley Rd
Woolloongabba QLD 4102

**Trial Email:** Nigel.Lee@mater.org.au
The transversus abdominis plane block, performed by an ultrasound or landmark technique, as part of the multimodal analgesic regimen for post caesarean analgesia

**Trial Question:** What is the efficacy of post operative analgesia provided by the transversus abdominis (TAP) block for woman undergoing caesarean section (CS) and how does analgesic efficacy and complications associated with the TAP block differ when it is performed using either an ultrasound guided approach or with a technique based on palpable landmarks

**Treatment Groups:** Women having elective CS under combined spinal epidural (CSE) anaesthesia randomised to the following groups: Ultrasound guided TAP block with intrathecal morphine and placebo TAP OR intrathecal placebo and active TAP OR intrathecal morphine and active TAP; landmark guided TAP block with intrathecal morphine and placebo TAP OR intrathecal placebo and active TAP OR intrathecal morphine and active TAP

<table>
<thead>
<tr>
<th>Trial Status: Not yet recruiting</th>
</tr>
</thead>
<tbody>
<tr>
<td>Single Centre Yes</td>
</tr>
<tr>
<td>Recruitment Target: 210</td>
</tr>
<tr>
<td>Coordinating Centre: King Edward Memorial Hospital for Women, Perth</td>
</tr>
</tbody>
</table>

**Chief Investigators:** Dr Nolan McDonnell, Professor Michael Paech

**Trial Contact:**
Dr Nolan McDonnell

**Contact Details:**
Dept of Anaesthetics and Pain Medicine
King Edward Memorial Hospital for Women
374 Bagot Road
Subiaco WA 6008

Tel: +61 8 9340 2250
Fax: +61 8 9340 2260

**Trial Email:**
nolan.mcdonnell@health.wa.gov.au
The COMMAND Trial

**Title:** Parecoxib, celecoxib and paracetamol for pain management following caesarean delivery.

ACTRN126090001041246

**Trial Question:** What is the quality of post-operative pain relief measured by epidural pethidine consumption provided by multimodal postoperative analgesic regimens?

<table>
<thead>
<tr>
<th>Treatment Groups:</th>
<th>1 – placebo vs 2 – COX-2 inhibitor vs 3 – paracetamol vs 4 – COX-2 inhibitors plus paracetamol</th>
</tr>
</thead>
</table>

In addition to Patient controlled epidural analgesia (PCEA) with pethidine for all women

**Trial Status:** Currently recruiting

**Single Centre**

Yes

**Recruitment Target:** 120

**Recruitment as at February 2012:** 108

**Coordinating Centre:** King Edward Memorial Hospital for Women, WA

**Chief Investigator:** Dr Michael Paech

**Trial contact:** Dr Michael Paech

**Contact Details:**
Dept of Anaesthesia & Pain Medicine
King Edward Memorial Hospital for Women
Bagot Road
Subiaco WA 6008

Tel: +61 8 9340 2222
Fax: +61 8 9340 2260

**Trial Email:** michael.paech@health.wa.gov.au
The Cycle Study

**Title:** A study of the effectiveness of cycling exercise in breaking the cycle of pregnancy diabetes.

NCT01283854

**Trial Question:** Would a 14 week supervised home-based exercise program (commenced at 14 weeks gestation) in women with gestational diabetes in a previous pregnancy prevent recurrence of gestational diabetes?

<table>
<thead>
<tr>
<th><strong>Treatment Groups:</strong></th>
<th>Three sessions per week of supervised home-based stationary cycling exercise and routine, regular antenatal care vs normal physical activity and routine, regular antenatal care</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Trial Status:</strong></td>
<td>Currently recruiting</td>
</tr>
<tr>
<td><strong>Single Centre:</strong></td>
<td>Yes</td>
</tr>
<tr>
<td><strong>Recruitment Target:</strong></td>
<td>200</td>
</tr>
<tr>
<td><strong>Recruitment as at February 2012:</strong></td>
<td>30</td>
</tr>
<tr>
<td><strong>Coordinating Centre:</strong></td>
<td>The University of Western Australia, WA</td>
</tr>
</tbody>
</table>

**Chief Investigator:** Professor John Newnham

**Trial Contact:** Dr Kym Guelfi

**Contact Details:**
University of Western Australia
Perth WA 6009

Tel: +61 8 6488 2602
Fax: +61 8 6488 1039

**Trial Email:**
John.Newnham@uwa.edu.au
kym.guelfi@uwa.edu.au
The Diary Trial

ACTRN12611001156976

**Trial Question:** Does a diary to record weight and diet help pregnant women achieve ideal weight gain in pregnancy and reduce gestational diabetes?

<table>
<thead>
<tr>
<th><strong>Treatment Groups:</strong></th>
<th>Diary given to pregnant women (at 20 weeks gestation) to document weight gain and diet vs routine best practice antenatal care</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Trial Status:</strong></td>
<td>Not yet recruiting</td>
</tr>
<tr>
<td><strong>Single Centre</strong></td>
<td>Yes</td>
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<td><strong>Recruitment Target:</strong></td>
<td>500</td>
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<tr>
<td><strong>Coordinating Centre:</strong></td>
<td>Joondalup Health Campus</td>
</tr>
</tbody>
</table>

**Chief Investigator:** Julie Quinlivan

**Trial Contact:** Julie Quinlivan

**Contact Details:**
Suite 112 Private Consulting Suites
Joondalup Health Campus
Shenton Ave
Joondalup WA 6027

Tel: +61 8 9400 9400
Fax: +61 8 9400 9955

**Trial Email:** quinlivanj@ramsayhealth.com.au
The impact of continuity of care on weight gain in obese pregnant women

ACTRN12610001078044

**Trial Question:** In obese pregnant women, does continuity of care compared to routine pregnancy care prevent excessive gestational weight gain?

<table>
<thead>
<tr>
<th>Treatment Groups:</th>
<th>Continuity of midwifery care throughout pregnancy vs usual care</th>
</tr>
</thead>
<tbody>
<tr>
<td>Trial Status:</td>
<td>Currently recruiting</td>
</tr>
<tr>
<td>Multi Centre</td>
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<tr>
<td>Recruitment Target:</td>
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<tr>
<td>Recruitment as at February 2012:</td>
<td>Deakin University, VIC</td>
</tr>
</tbody>
</table>

**Coordinating Centre:** Deakin University, VIC

**Chief Investigator:** Dr Cate Nagle

**Trial Contact:** Dr Cate Nagle

**Contact Details:** School of Nursing and Midwifery
Geelong Waterfront Campus
Geelong Vic 3217

Tel: +61 3 5227 8401
Fax: +61 3 5227 8411

**Trial Email:** cate.nagle@deakin.edu.au
The POPOUT Study

Title: Persistent Occipito-Posterior: Outcomes following digital rotation

ACTRN126090000985280

Trial Question: Does manual rotation to occipito-posterior position reduce the operative birth rates (forceps, ventouse, caesarean)?

<table>
<thead>
<tr>
<th>Treatment Groups:</th>
<th>Digital rotation vs standard care</th>
</tr>
</thead>
<tbody>
<tr>
<td>Trial Status:</td>
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<tr>
<td>Single Centre-</td>
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<td>Recruitment Target:</td>
<td>254</td>
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<tr>
<td>Coordinating Centre:</td>
<td>Royal Prince Alfred Hospital, NSW</td>
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</tbody>
</table>

Chief Investigator: Hala Phipps

Trial contact: Hala Phipps

Contact Details:
Building 89, Level 5 East
C/- RPA Women and Babies
Royal Prince Alfred Hospital
Missenden Road
Camperdown NSW 2050

Tel: +61 2 9515 6079
Fax: +61 2 9565 1595
Title: Thrombophilia in Pregnancy Prophylaxis Study: a multicentre, multinational randomised controlled trial of prophylactic low molecular weight heparin in high-risk pregnant thrombophilic women

ISRCTN87441504; ACTRN12608000446369

Trial Question: Would a drug to prevent clotting (dalteparin) given through pregnancy prevent pregnancy complications?

<table>
<thead>
<tr>
<th>Treatment Groups:</th>
<th>Dalteparin vs no treatment</th>
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</table>

<table>
<thead>
<tr>
<th>Trial Status:</th>
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<table>
<thead>
<tr>
<th>Multi Centre:</th>
<th>Currently 26 active sites in Canada, USA, UK and Australia</th>
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<table>
<thead>
<tr>
<th>Additional Centres Needed:</th>
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<th>285</th>
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<table>
<thead>
<tr>
<th>Coordinating Centre:</th>
<th>Ottawa Health Research Institute, The Ottawa Hospital, Canada</th>
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</thead>
</table>

<table>
<thead>
<tr>
<th>Centres in Australia Currently Recruiting:</th>
<th>SA - Women's &amp; Children's Hospital, Adelaide:</th>
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</thead>
<tbody>
<tr>
<td></td>
<td>VIC - The Royal Women's Hospital, Melbourne:</td>
</tr>
</tbody>
</table>

More collaborating centres needed

Chief Investigator: Dr Marc Rodger (Canada)

Australian Principal Investigator: Professor Bill Hague

Australian Coordinator: Suzette Coat

Australian Trial Contact: Professor Bill Hague
(bill.hague@adelaide.edu.au)
Suzette Coat (suzette.coat@adelaide.edu.au)

Contact Details: The Ottawa Hospital
General Campus
501 Smyth Road
Ottawa
Canada K1H 8L6

Canadian Trial contact: Daphne Towers - Coordinator

Trial Email: dtowers@ohri.ca

Trial Website: http://www.healthypregnancy.ca
Using the Internet to support breastfeeding duration

Title: Evaluating the use of an Internet intervention to sustain breastfeeding duration for primiparous and multiparous mothers in regional Western Australia.

ACTRN12610000062022

Trial Question: Would women in regional WA with access to high level of support through the internet increase breastfeeding?

<table>
<thead>
<tr>
<th>Treatment Groups:</th>
<th>Access to breastfeeding support on internet website vs no access to internet website (with standard postnatal support)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Trial Status:</td>
<td>Not yet recruiting</td>
</tr>
<tr>
<td>Single Centre-</td>
<td>Yes</td>
</tr>
<tr>
<td>Recruitment Target:</td>
<td>300</td>
</tr>
<tr>
<td>Coordinating Centre:</td>
<td>WACHPR, School of Public Health, Curtin University of Technology</td>
</tr>
</tbody>
</table>

Chief Investigator: Roslyn Giglia

Trial Contact: Roslyn Giglia

Contact Details:
WACHPR
School of Public Health
GPO Box u1987
Perth WA 6845

Tel: +61 8 9266 7382
Fax: +61 8 9266 2958

Trial Email: R.Giglia@exchange.curtin.edu.au
Title: Walking for Exercise and Nutrition to prevent Diabetes for You

ACTRN12611000075987, NCT01247753

Trial Question: Is an exercise and nutrition program more effective than standard care in terms of weight loss and increased regular activity to prevent type 2 diabetes in overweight women previously diagnosed with gestational diabetes mellitus?

<table>
<thead>
<tr>
<th>Treatment Groups:</th>
<th>Exercise and nutrition program vs standard care</th>
</tr>
</thead>
<tbody>
<tr>
<td>Trial Status:</td>
<td>Currently recruiting</td>
</tr>
<tr>
<td>Single Centre:</td>
<td>Yes</td>
</tr>
<tr>
<td>Recruitment Target:</td>
<td>102</td>
</tr>
<tr>
<td>Recruitment as at February 2012:</td>
<td>19</td>
</tr>
<tr>
<td>Coordinating Centre:</td>
<td>Mater Medical Research Centre, Mater Health Services; University of Queensland School of Nursing and Midwifery</td>
</tr>
</tbody>
</table>

Chief Investigator: Ann Peacock

Trial Contact: Ann Peacock

Contact Details: Mater Mothers’ Research Centre
Level 3 Aubigny Place
Raymond Terrace
South Brisbane QLD 4101

Tel: +61 7 3163 2874

Trial Email: apeacock@mmri.mater.org.au
Title: Weighing In Pregnancy

ACTRN12610000331033

**Trial Question:** Does weighing antenatal women at each routine antenatal visit reduce the incidence of excessive weight gain during pregnancy?

<table>
<thead>
<tr>
<th><strong>Treatment Groups:</strong></th>
<th>Weighing included at each visit for routine antenatal check vs routine antenatal care.</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Trial Status:</strong></td>
<td>Currently recruiting</td>
</tr>
<tr>
<td><strong>Single Centre:</strong></td>
<td>Yes</td>
</tr>
<tr>
<td><strong>Recruitment Target:</strong></td>
<td>650</td>
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<td><strong>Recruitment as at February 2012:</strong></td>
<td></td>
</tr>
<tr>
<td><strong>Coordinating Centre:</strong></td>
<td>The Royal Women's Hospital, Melbourne</td>
</tr>
<tr>
<td><strong>Centres in Australia Currently Recruiting:</strong></td>
<td>The Royal Women's Hospital, Melbourne VIC</td>
</tr>
</tbody>
</table>

**Chief Investigator:** Dr Fiona Brownfoot

**Trial Contact:** Dr Fiona Brownfoot

**Contact Details:** The Royal Women's Hospital, Grattan St & Flemington Road, Parkville VIC 3052

**Trial Email:** fiona.brownfoot@thewomens.org.au
Neonatal Trials
ACDC

Aboriginal Cord Delayed Clamping Study - pilot

ACTRN12612000071820

**Trial Question:** Will haemoglobin level at discharge be greater in term Aboriginal babies from remote communities after delayed cord clamping ≥1 to ≤3 minutes compared with immediate cord clamping <1 minute?

<table>
<thead>
<tr>
<th>Treatment Groups:</th>
<th>Cord clamping when the cord stops pulsating or at least 1 minute and no more than 3 minutes after delivery vs immediate cord clamping (within 1 minute)</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>Trial Status:</th>
<th>Currently recruiting</th>
</tr>
</thead>
<tbody>
<tr>
<td>Single Centre:</td>
<td>Yes</td>
</tr>
<tr>
<td>Recruitment Target:</td>
<td>72</td>
</tr>
<tr>
<td>Recruitment as at February 2012:</td>
<td>3</td>
</tr>
<tr>
<td>Coordinating Centre:</td>
<td>Menzies School of Health Research</td>
</tr>
</tbody>
</table>

**Chief Investigator:** Dr Melanie Hanson

**Trial Contact:** Dr Melanie Hanson

**Contact Details:**
Paediatric Department  
Royal Darwin Hospital  
Rocklands Drive  
Tiwi NT 0180

Tel: +61 8 8922 8888  
Fax: +61 8 8927 5187

**Trial Email:**  
Melanie.hanson@menzies.edu.au
Title: Australian Placental Transfusion Study

NHMRC571309; ACTRN12610000633088

Trial Question: Should very premature babies receive a placental transfusion at birth?

<table>
<thead>
<tr>
<th>Treatment Groups:</th>
<th>Autologous placental transfusion (deferred cord clamping) vs standard early cord clamping</th>
</tr>
</thead>
<tbody>
<tr>
<td>Trial Status:</td>
<td>Currently recruiting</td>
</tr>
<tr>
<td>Multi Centre:</td>
<td>Yes</td>
</tr>
<tr>
<td>Additional Centres Needed:</td>
<td>Yes</td>
</tr>
<tr>
<td>Recruitment Target:</td>
<td>1600</td>
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<tr>
<td>Recruitment as at February 2012:</td>
<td>112</td>
</tr>
<tr>
<td>Coordinating Centre:</td>
<td>NHMRC Clinical Trials Centre, The University of Sydney, NSW</td>
</tr>
<tr>
<td>Centres in Australia Currently Recruiting:</td>
<td>Royal Prince Alfred Hospital, NSW&lt;br&gt;Royal North Shore Hospital, NSW&lt;br&gt;John Hunter Hospital, NSW&lt;br&gt;Monash Medical Centre, VIC&lt;br&gt;Flinders Medical Centre, SA&lt;br&gt;Townsville Hospital, QLD&lt;br&gt;King Edward Memorial Hospital, WA</td>
</tr>
</tbody>
</table>

Chief Investigator: Professor William Tarnow-Mordi

Trial Contact: Dr Lucille Sebastian

Contact Details: Australian Placental Transfusion Study<br>NHMRC Clinical Trials Centre<br>Locked Bag 77<br>Camperdown NSW 1450

Tel: + 61 2 9562 5335<br>Fax: +61 2 9565 1863

Trial Email: apts@ctc.usyd.edu.au
Title: Impact of probiotics on infant colic and parent mental health. A randomised double-blinded, placebo-controlled trial in breast and formula fed infants less than 3 months old.

ISRCTN95287767

Trial Question: Do probiotics help crying babies with reducing infant colic, and also help their families?

<table>
<thead>
<tr>
<th>Treatment Groups:</th>
<th>Probiotic Lactobacillus reuteri in an oil suspension vs placebo</th>
</tr>
</thead>
<tbody>
<tr>
<td>Trial Status:</td>
<td>Currently recruiting</td>
</tr>
<tr>
<td>Single Centre</td>
<td>Yes</td>
</tr>
<tr>
<td>Recruitment Target:</td>
<td>160</td>
</tr>
<tr>
<td>Recruitment as at February 2012:</td>
<td></td>
</tr>
<tr>
<td>Coordinating Centre:</td>
<td>Royal Children's Hospital, VIC</td>
</tr>
</tbody>
</table>

Chief Investigator: Dr Valerie Sung

Trial Contact: Dr Valerie Sung

Contact Details: Centre for Community Child Health Royal Children’s Hospital Flemington Road Parkville Vic 3052

Trial Email: valerie.sung@rch.org.au
**Title:** An open label, randomised, controlled pilot study to evaluate the safety and efficacy of aerosolised surfactant in the first hour of life in preterm infants with respiratory distress syndrome (RDS)

ACTRN1261000085700

**Trial Question:** Would the use of a nebulised surfactant to treat preterm babies with moderate respiratory disease reduce the need for intubation?

<table>
<thead>
<tr>
<th>Treatment Groups:</th>
<th>Nebulisation of aerosolised surfactant vs standard treatment via intubation.</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Trial Status:</strong></td>
<td>Currently recruiting</td>
</tr>
<tr>
<td><strong>Single Centre</strong></td>
<td>Yes</td>
</tr>
<tr>
<td><strong>Recruitment Target:</strong></td>
<td>110</td>
</tr>
<tr>
<td><strong>Recruitment as at February 2012:</strong></td>
<td>King Edward Memorial Hospital, WA</td>
</tr>
</tbody>
</table>

**Chief Investigator:** Professor J J Pillow

**Trial Contact:** Dr Stefan Minocchieri

**Contact Details:**
King Edward Memorial Hospital  
Neonatal Special Care Nursery  
Bagot Rd  
Subiaco WA 6008

Tel: +61 8 9340 8452

**Trial Email:**
jpillow@meddment.uwa.edu.au  
sminocchieri@meddment.uwa.edu.au
**Title:** Ductal Echocardiographic Targeting and Early Closure Trial

ACTRN12608000295347

**Trial Question:** Does selection and early treatment of a subgroup of preterm infants, with a high likelihood of a persisting ductus arteriosus based on an early ultrasound demonstrating failure of early ductal constriction, improve medium term nursery outcomes.

<table>
<thead>
<tr>
<th>Treatment Groups:</th>
<th>Early targeted indomethacin vs placebo</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Trial Status:</strong></td>
<td>Currently recruiting</td>
</tr>
<tr>
<td><strong>Multi Centre:</strong></td>
<td>Three Australian centres participating</td>
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<tr>
<td><strong>Additional Centres Needed:</strong></td>
<td>Yes</td>
</tr>
<tr>
<td><strong>Recruitment Target:</strong></td>
<td>370</td>
</tr>
<tr>
<td><strong>Recruitment as at February 2012:</strong></td>
<td>160</td>
</tr>
<tr>
<td><strong>Coordinating Centre:</strong></td>
<td>Royal North Shore Hospital, Sydney</td>
</tr>
</tbody>
</table>

**Centres in Australia Currently Recruiting:**
- Royal North Shore Hospital, NSW
- Royal Prince Alfred Hospital, NSW
- King Edward Memorial Hospital, WA

**Chief Investigator:** Assoc/Professor Martin Kluckow

**Trial Contact:** Assoc/Professor Martin Kluckow

**Contact Details:**
Royal North Shore Hospital  
St Leonards NSW 2065

**Trial Email:** mkluckow@med.usyd.edu.au

Tel: +61 2 9926 7509
Effect of position during bottle feeding on physiological stability in preterm infants

ACTRN12611000944932

**Trial Question:** Will a side lying position for bottle feeding preterm babies compared with a cradle hold position improve baby's breathing and heart rate?

<table>
<thead>
<tr>
<th>Treatment Groups:</th>
<th>Side lying position bottle feed vs standard cradle hold position</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Trial Status:</strong></td>
<td>Currently recruiting</td>
</tr>
<tr>
<td>Single Centre</td>
<td>Yes</td>
</tr>
<tr>
<td>Recruitment Target:</td>
<td>30</td>
</tr>
<tr>
<td>Recruitment as at February 2012:</td>
<td>24</td>
</tr>
<tr>
<td>Coordinating Centre:</td>
<td>The Royal Women's Hospital, Melbourne</td>
</tr>
<tr>
<td>Centres in Australia Currently Recruiting:</td>
<td>The Royal Women's Hospital, Melbourne VIC</td>
</tr>
</tbody>
</table>

**Chief Investigator:** Dr Jennifer Dawson

**Trial Contact:** Dr Jennifer Dawson

**Contact Details:**
Newborn Research
The Royal Women's Hospital
Grattan St & Flemington Road
Parkville VIC 3052

Tel: +61 3 8345 3791
Fax: +61 3 8345 3789

**Trial Email:**
jenennifer.dawson@thewomens.org.au
Title: Efficacy and safety of SMOFlipid compared with Clinoleic in preterm (<30 weeks) neonates – a randomised controlled trial

ACTRN12609001017213

Trial Question: To test the safety and efficacy of new fish oil based intravenous fat emulsion to traditional olive oil based intravenous fat emulsion, in preterm neonates (<30 weeks).

<table>
<thead>
<tr>
<th>Treatment Groups:</th>
<th>SMOFlipid intravenous lipid emulsion vs Clinoleic intravenous lipid emulsion.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Trial Status:</td>
<td>Currently recruiting</td>
</tr>
<tr>
<td>Single Centre</td>
<td>Yes</td>
</tr>
<tr>
<td>Recruitment Target:</td>
<td>30</td>
</tr>
<tr>
<td>Recruitment as at February 2012:</td>
<td>4</td>
</tr>
<tr>
<td>Coordinating Centre:</td>
<td>King Edward Memorial Hospital for Women, WA</td>
</tr>
</tbody>
</table>

Chief Investigator: Dr Girish Deshpande

Trial Contact: Dr Girish Deshpande

Contact Details: Department of Neonatal Paediatrics  
King Edward Memorial Hospital for Women  
374 Bagot Rd  
Subiaco WA 6008

Tel: + 61 8 9340 2222  
Fax: + 61 8 9340 1262

Trial Email: drgirishdeshpande@gmail.com
Efficacy and safety of a novel fish oil based lipid emulsion (SMOFlipid) compared with olive oil based lipid emulsion (Clinoleic) in neonates >34 weeks

**Title:** Efficacy and safety of a novel fish oil based lipid emulsion (SMOFlipid emulsion (Clinoleic) in neonates >34 weeks.

ACTRN12609000337279

**Trial Question:** To compare effect of new fish oil based intravenous fat emulsion with olive oil emulsion in term and near term neonates on LC-PUFA levels

<table>
<thead>
<tr>
<th>Treatment Groups:</th>
<th>SMOFlipid intravenous lipid emulsion vs Clinoleic intravenous lipid emulsion</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Trial Status:</strong></td>
<td>Currently recruiting</td>
</tr>
<tr>
<td><strong>Single Centre</strong></td>
<td>Yes</td>
</tr>
<tr>
<td><strong>Recruitment Target:</strong></td>
<td>40</td>
</tr>
<tr>
<td><strong>Recruitment as at February 2012:</strong></td>
<td>12</td>
</tr>
<tr>
<td><strong>Coordinating Centre:</strong></td>
<td>Princess Margaret Hospital for Children, WA</td>
</tr>
</tbody>
</table>

**Chief Investigator:** Dr Girish Deshpande

**Trial Contact:** Dr Girish Deshpande

**Contact Details:**
Department of Neonatal Paediatrics
Princess Margaret Hospital for Children
Roberts Road
Subiaco WA 6008

Tel +61 8 9340 8222

**Trial Email:** girish.deshpande@health.wa.gov.au
Fetal lactate measurement to reduce caesarean sections during labour: a randomised trial

ACTRN12611000172909

**Trial Question:** Does a lactate test in addition to standard monitoring of the fetal heart rate by cardiotocography make a difference in the number of women having caesarean births?

<table>
<thead>
<tr>
<th><strong>Treatment Groups:</strong></th>
<th>Addition of fetal blood sampling for lactate measurement during labour and monitoring of fetal heart rate by cardiotocography vs standard monitoring of fetal heart rate by cardiotocography only</th>
</tr>
</thead>
</table>

**Trial Status:** Recruitment to commence 2012

**Single Centre**

Yes

**Recruitment Target:** 600

**Coordinating Centre:** Royal Women’s Hospital, VIC

**Chief Investigator:** Dr Christine East

**Trial Contact:** Dr Christine East

**Contact Details:**
Royal Women's Hospital  
20 Flemington Road  
Parkville Vic 3052

Tel: +61 3 8345 3700  
Fax: +61 3 8345 3702

**Trial Email:** eastc@unimelb.edu.au
Title: Flows at lower rates

ACTRN12611000628943

Trial Question: Does lower bias gas flow in ventilated preterm babies reduce the risk of lung injury and bronchopulmonary dysplasia?

<table>
<thead>
<tr>
<th>Treatment Groups:</th>
<th>Ventilation via endotracheal tube at a bias gas flow of 4L/min (arm 1) or 10L/min (arm 2) vs standard ventilation at a bias gas flow of 10L/min</th>
</tr>
</thead>
<tbody>
<tr>
<td>Trial Status:</td>
<td>Not yet recruiting</td>
</tr>
<tr>
<td>Multi Centre</td>
<td>Australia and New Zealand</td>
</tr>
<tr>
<td>Recruitment Target:</td>
<td>180</td>
</tr>
<tr>
<td>Coordinating Centre:</td>
<td>Liggins Institute, University of Auckland</td>
</tr>
<tr>
<td>Centres in Australia Currently Recruiting:</td>
<td>Royal Women's Hospital, VIC</td>
</tr>
</tbody>
</table>

Chief Investigator: Assoc/Professor Frank Bloomfield

Trial Contact: Dr Katinka Bach

Contact Details: Newborn Services
Auckland City Hospital,
Support Building, Level 9
PO Box 92024
AUCKLAND 1023
New Zealand

Tel: +61 21 064 3439
Fax: +64 9 3754373

Trial Email: f.bloomfield@auckland.ac.nz
kittyb@adhb.govt.nz
**GAS Study**

**Title:** A multi-site randomised controlled trial comparing bupivacaine (regional) anaesthesia versus sevoflurane (general) anaesthesia for effects on neurodevelopmental outcome and apnoea in infants scheduled for unilateral or bilateral inguinal hernia repair

ACTRN012606000441516; NCT00756600

**Trial Question:** Do different types of anaesthesia given to infants undergoing inguinal hernia repair result in equivalent neurodevelopmental outcomes?

<table>
<thead>
<tr>
<th>Treatment Groups:</th>
<th>General anaesthesia (sevoflurane) vs regional anaesthesia (either: spinal block alone, spinal and caudal block, spinal and ilioinguinal block, caudal block alone)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Trial Status:</strong></td>
<td>Currently recruiting</td>
</tr>
<tr>
<td><strong>Multi Centre:</strong></td>
<td>National and International.</td>
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<td><strong>Additional Centres Needed:</strong></td>
<td>Yes</td>
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<td><strong>Recruitment Target:</strong></td>
<td>660</td>
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<tr>
<td><strong>Recruitment as at February 2012:</strong></td>
<td>565</td>
</tr>
<tr>
<td><strong>Coordinating Centre:</strong></td>
<td>Department of Anaesthesia, Royal Children's Hospital</td>
</tr>
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</table>
| **Centres in Australia Currently Recruiting:** | SA – Women's and Children's Hospital, Adelaide  
VIC – Royal Children's Hospital, Melbourne  
Monash Medical Centre, Melbourne  
Cabrini Hospital, Melbourne  
Casey Hospital, Melbourne  
WA – Princess Margaret Hospital, Perth |

**Steering Committee:** Chair: Paul Myles (Melbourne), David Bellinger (Boston), Charles Berde (Boston), John Carlin (Melbourne), Andrew Davidson (Melbourne), Rod Hunt (Melbourne), Mary Ellen McCann (Boston), Neil Morton (Glasgow), Neil McIntosh (Edinburgh), Kate Leslie (Melbourne), Andy Wolf (Bristol), Nicola Disma (Genoa), Davinia Withington (Montreal)

**Trial Contact:** Suzette Sheppard

**Contact Details:**  
Department of Anaesthesia  
Royal Children's Hospital  
Flemington Road  
Parkville Vic 3052

tel: +61 3 9345 5233  
Fax: +61 3 9345 6003

**Trial Email:**  
gillian.ormond@mcri.edu.au  
suzette.sheppard@mcri.edu.au  
andrew.davidson@rch.org.au
GI Baby 3

**Title:** A dietary intervention during pregnancy to reduce child obesity – a randomized, controlled trial.

ACTRN12610000681055

**Trial Question:** What is the effect of a low glycemic diet compared with a wholegrain high fibre diet on infant birth weight and body composition, related to GDM and progression to GDM diagnosis in pregnant women at high-risk of GDM?

<table>
<thead>
<tr>
<th>Treatment Groups:</th>
<th>Low glycemic index diet vs wholegrain high fibre diet</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Trial Status:</strong></td>
<td>Currently recruiting</td>
</tr>
<tr>
<td><strong>Single Centre</strong></td>
<td>Yes</td>
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<tr>
<td><strong>Recruitment Target:</strong></td>
<td>150</td>
</tr>
<tr>
<td><strong>Recruitment as at February 2012:</strong></td>
<td>8</td>
</tr>
<tr>
<td><strong>Coordinating Centre:</strong></td>
<td>School of Molecular and Microbial Biosciences, The University of Sydney</td>
</tr>
</tbody>
</table>

**Chief Investigator:** Professor Jennie Brand-Miller

**Trial Contact:** Dawn Tan

**Contact Details:**
Room 447, Human Nutrition Unit  
School of Molecular and Microbial Biosciences  
The University of Sydney NSW 2006

Tel: +61 2 9351 3759  
Fax: + 61 2 9351 6022

**Trial Email:**
j.brandmiller@usyd.edu.au

**Trial Contact:**
dawn.tan@sydney.edu.au
HiFloW Trial

**Title:** Heated humidified high flow nasal cannula for weaning from nasal continuous positive airway pressure trial in preterm infants

ACTRN12610001003066

**Trial Question:** Which method of weaning from CPAP is most effective at reducing the length of hospital stay, facilitating infant suck feeding and improving parent-infant interaction?

**Treatment Groups:**
- Abrupt weaning from nasal continuous positive airway pressure to heated, humidified high flow nasal cannula (HHHFNC) vs
- Abrupt weaning from nCPAP without HHHFNC vs
- Gradual weaning from nCPAP to HHHFNC vs
- Gradual weaning from nCPAP without HHHFNC

**Trial Status:** Currently recruiting

<table>
<thead>
<tr>
<th>Single Centre</th>
<th>Yes</th>
</tr>
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<tbody>
<tr>
<td>Recruitment Target:</td>
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<tr>
<td>Recruitment as at February 2012:</td>
<td>45</td>
</tr>
<tr>
<td>Coordinating Centre:</td>
<td>RPA Newborn Care, Royal Prince Alfred Hospital, NSW</td>
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</table>

**Chief Investigator:** Assoc/Professor David Osborn

**Trial Contact:** Assoc/Professor David Osborn

**Contact Details:**
RPA Newborn Care
Royal Prince Alfred Hospital
Missenden Road
Camperdown NSW 2050

**Tel:** +61 2 9515 8363

**Trial Email:** david.osborn@email.cs.nsw.gov.au
Title: High-flow nasal cannulae as post-extubation respiratory support for premature infants: A CPAP equivalent? (The HIPERSPACE Trial)

ACTRN1261000016077

Trial Question: What is the failure rate of high flow nasal cannulae (HFNC) compared with nasal continuous positive airway pressure (CPAP) for post-extubation respiratory support in preterm infants <32 weeks’ gestation?

<table>
<thead>
<tr>
<th>Treatment Groups:</th>
<th>High-flow nasal cannulae (HFNC) vs Nasal CPAP</th>
</tr>
</thead>
<tbody>
<tr>
<td>Trial Status:</td>
<td>Currently recruiting</td>
</tr>
<tr>
<td>Multi Centre:</td>
<td>Yes</td>
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<tr>
<td>Recruitment Target:</td>
<td>300</td>
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<tr>
<td>Recruitment as at February 2012:</td>
<td>185</td>
</tr>
<tr>
<td>Coordinating Centre:</td>
<td>Royal Women’s Hospital, Melbourne</td>
</tr>
</tbody>
</table>

Chief Investigators: Dr Brett Manley, Ms Connie Wong, Dr Chad Andersen, Dr Margo Pritchard, Dr David Cartwright, Assoc/Professor Susan Donath, Professor Peter Davis, Professor Lex Doyle, Dr Louise Owen

Trial Contact: Dr Brett Manley

<table>
<thead>
<tr>
<th>Contact Details:</th>
<th>Trial Email:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Department of Newborn Research</td>
<td></td>
</tr>
<tr>
<td>Level 7, Royal Women’s Hospital</td>
<td></td>
</tr>
<tr>
<td>20 Flemington Road</td>
<td></td>
</tr>
<tr>
<td>Parkville VIC 3052</td>
<td><a href="mailto:brett.manley@thewomens.org.au">brett.manley@thewomens.org.au</a></td>
</tr>
</tbody>
</table>

Tel: +61 3 8345 3766
Humidity in incubators for preterm infants

**Title:** Humidity in incubators for preterm infants

PT0541

**Trial Question:** What is the optimal level and duration of incubator humidity in the management of preterm infants? What are the effects of humidification on clinically important outcomes?

**Treatment Groups:**

**Trial Status:** Not yet recruiting

**Single Centre**

**Recruitment Target:**

**Coordinating Centre:**

**Chief Investigators:** Lynn Sinclair, John Sinn

**Trial Contact:** Lynn Sinclair

**Contact Details:**
Lynn Sinclair
Tel: +61 2 9845 8702

John Sinn
Tel: +61 2 9845 8748

**Trial Email:** lynn_sinclair@wsahs.nsw.gov.au
Immunogenicity and safety of acellular pertussis vaccine at birth

ACTRN12609000905268

**Trial Question:** Are babies better protected if given the pertussis vaccine earlier than 6 weeks old?

<table>
<thead>
<tr>
<th>Treatment Groups:</th>
<th>Pertussis and hepatitis vaccine vs hepatitis vaccine, shortly after birth</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Trial Status:</strong></td>
<td>Currently recruiting</td>
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<tr>
<td><strong>Multi Centre</strong></td>
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<td><strong>Additional Centres Needed:</strong></td>
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<td><strong>Recruitment Target:</strong></td>
<td>440</td>
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<tr>
<td><strong>Recruitment as at February 2012:</strong></td>
<td>200</td>
</tr>
<tr>
<td><strong>Coordinating Centre:</strong></td>
<td>Royal Alexandra Hospital for Children, Westmead</td>
</tr>
</tbody>
</table>
| **Centres Currently Recruiting:** | The Children’s Hospital at Westmead, NSW  
Women’s and Children’s Hospital, SA  
Murdoch Children’s Research Institute, VIC  
Princess Margaret Hospital for Children, WA |

**Chief Investigator:** Dr Nicholas Wood

**Trial Contact:** Dr Nicholas Wood

**Contact Details:**
The Children’s Hospital at Westmead  
NCIRS Locked Bag 4001  
Westmead NSW 2145

Tel: +61 2 9845 1433  
Fax: +61 2 9845 1418

**Trial Email:** NicholW3@chw.edu.au
Title: Lactoferrin Infant Feeding Trial to prevent sepsis and death in preterm infants.

ACTRN12611000247976

Trial Question: Does bovine lactoferrin prevent sepsis and death in preterm infants?

<table>
<thead>
<tr>
<th>Treatment Groups:</th>
<th>Bovine lactoferrin 150 mg/kg/day dissolved in breastmilk or formula vs standard feeding regimens</th>
</tr>
</thead>
<tbody>
<tr>
<td>Trial Status:</td>
<td>Not yet recruiting</td>
</tr>
<tr>
<td>Single Centre:</td>
<td>Yes</td>
</tr>
<tr>
<td>Recruitment Target:</td>
<td>1000</td>
</tr>
<tr>
<td>Coordinating Centre:</td>
<td>NHMRC Clinical Trial Centre, NSW</td>
</tr>
</tbody>
</table>

Chief Investigator: Professor William Tarnow-Mordi

Trial Contact: Alpana Ghadge

Contact Details: 
NHMRC Clinical Trials Centre  
Locked Bag 77  
Camperdown NSW 1450

Trial Email:  
williamtm@med.usyd.edu.au  
alpana.ghadge@cts.usyd.edu.au

Tel: +61 2 9562 5000
MONT Trial

**Title:** A randomised controlled trial of mask versus nasal tube for the stabilisation of preterm infants (born between 24 and 29 complete weeks gestation) in the delivery room.

ACTRN12610000230055

**Trial Question:** In extremely premature infants receiving help to establish breathing, is mask or nasal tube CPAP more effective in stabilising the lungs?

**Treatment Groups:**
Nasal tube to deliver continuous positive airway pressure CPAP vs face mask to deliver continuous positive airway pressure CPAP

**Trial Status:**
Currently recruiting

**Single Centre**
Yes

**Recruitment Target:**
648

**Recruitment as at February 2012:**

**Coordinating Centre:**
Newborn Services and Neonatal Research, Royal Women’s Hospital

**Chief Investigator:** Omar Kamlin

**Trial Contact:** Omar Kamlin

**Contact Details:**
Newborn Services and Neonatal Research 7th Floor Royal Women’s Hospital 20 Flemington Road Parkville VIC 3052

Tel: +61 3 8345 3769
Fax: +61 3 8345 3789

**Trial Email:**
omar.kamlin@thewomens.org.au
Optimist-B

Multicentre randomised controlled trial of minimally-invasive surfactant therapy in preterm infants 29-32 weeks gestation on continuous positive airway pressure

ACTRN12611000917932

**Trial Question:** Does administration of exogenous surfactant using a minimally-invasive technique improve outcome in preterm infants 29-32 weeks gestation treated with continuous positive air pressure (CPAP)?

<table>
<thead>
<tr>
<th>Treatment Groups:</th>
<th>Minimally-invasive surfactant therapy vs standard care</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Trial Status:</strong></td>
<td>Not yet recruiting</td>
</tr>
<tr>
<td><strong>Multi Centre:</strong></td>
<td>Yes</td>
</tr>
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<td><strong>Recruitment Target:</strong></td>
<td>454</td>
</tr>
<tr>
<td><strong>Coordinating Centre:</strong></td>
<td>Royal Hobart Hospital, Tasmania</td>
</tr>
</tbody>
</table>

**Chief Investigator:** Assoc/Professor Peter Dargaville

**Trial Contact:** Karen Butterley

**Contact Details:**
Royal Hobart Hospital
Liverpool Street
Hobart TAS 7000

**Trial Email:** Karen.butterley@dhhs.tas.gov.au

Tel: +61 3 62222 7546
**PDA Trial**

Paracetamol Duct Action

ACTRN12611000741987

**Trial Question:** Does paracetamol close a patent ductus arteriosus in preterm infants?

<table>
<thead>
<tr>
<th>Treatment Groups:</th>
<th>Oral paracetamol vs placebo on ductal closure in premature infants aged &gt; 2 weeks and born before 33 weeks of gestation</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Trial Status:</strong></td>
<td>Currently recruiting</td>
</tr>
<tr>
<td><strong>Single Centre</strong></td>
<td>Yes</td>
</tr>
<tr>
<td><strong>Recruitment Target:</strong></td>
<td>60</td>
</tr>
<tr>
<td><strong>Coordinating Centre:</strong></td>
<td>Royal North Shore Hospital, NSW</td>
</tr>
</tbody>
</table>

**Chief Investigator:** Assoc/Professor Martin Kluckow

**Trial Contact:** Assoc/Professor Martin Kluckow

**Contact Details:**
Department of Neonatology  
Level 5, Douglas Building  
Royal North Shore Hospital  
Pacific Highway  
St Leonards NSW 2065

**Tel:** +61 2 9926 7509

**Trial Email:** mkluckow@med.usyd.edu.au
**POPPET**

Providing Optimal Protein for Prems via Enteral Tubes

ACTRN12611001275954

**Trial Question:** Does increasing the protein content of human milk fortifier improve growth in preterm infants <33 weeks gestation?

<table>
<thead>
<tr>
<th>Treatment Groups:</th>
<th>Increased protein content in human milk fortifier vs standard protein fortification</th>
</tr>
</thead>
<tbody>
<tr>
<td>Trial Status:</td>
<td>Currently recruiting</td>
</tr>
<tr>
<td>Single Centre</td>
<td>Yes</td>
</tr>
<tr>
<td>Recruitment Target:</td>
<td>60</td>
</tr>
<tr>
<td>Recruitment as at February 2012:</td>
<td>3</td>
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</table>

**Coordinating Centre:**

Women's and Children's Health Research Institute, Women's & Children's Hospital, SA

**Chief Investigator:** Jessica Reid

**Trial Contact:** Jessica Reid

**Contact Details:**

WCHRI
72 King William Road
North Adelaide SA 5006

Tel: +61 8 8161 6848

**Trial Email:** Jessica.reid@adelaide.edu.au
Prevention of hypothermia in the delivery room for preterm infants <30 weeks gestation

**Title:** Prevention of hypothermia in the delivery room for preterm infants <30 weeks gestation

**Trial Question:** Is the plastic wrapping of premature neonates in birth suite a more effective method of preventing hypothermia than the traditional method?

<table>
<thead>
<tr>
<th>Treatment Groups:</th>
<th>Plastic wrapping vs conventional method</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Trial Status:</strong></td>
<td>Currently recruiting</td>
</tr>
<tr>
<td><strong>Single Centre</strong></td>
<td>Yes</td>
</tr>
<tr>
<td><strong>Recruitment Target:</strong></td>
<td>86</td>
</tr>
<tr>
<td><strong>Recruitment as at February 2012:</strong></td>
<td>62</td>
</tr>
<tr>
<td><strong>Coordinating Centre:</strong></td>
<td>Department of Neonatology, Townsville Hospital, QLD</td>
</tr>
</tbody>
</table>

**Chief Investigator:** Dr Gary Alcock

**Trial Contact:** Ms Jacqueline Smith

**Contact Details:**
Neonatology Dept
Townsville Hospital
Townsville Qld 4810

**Tel:** + 61 7 4796 1111

**Trial Email:** jacquelineJ_smith@health.qld.gov.au
Propofol compared to morphine and midazolam for facilitating neonatal intubation: a randomised, controlled trial

ACTRN12608000277347

**Trial Question:** Does propofol ease intubation in neonates compared to morphine and midazolam?

<table>
<thead>
<tr>
<th>Treatment Groups:</th>
<th>Propofol vs morphine and midazolam</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Trial Status:</strong></td>
<td>Currently recruiting</td>
</tr>
<tr>
<td><strong>Single Centre</strong></td>
<td>Yes</td>
</tr>
<tr>
<td><strong>Recruitment Target:</strong></td>
<td>60</td>
</tr>
<tr>
<td><strong>Recruitment as at February 2012:</strong></td>
<td>30</td>
</tr>
<tr>
<td><strong>Coordinating Centre:</strong></td>
<td>Grantley Stable Neonatal Unit, Royal Brisbane and Women's Hospital, Brisbane</td>
</tr>
</tbody>
</table>

**Chief Investigator:** Dr Pieter Koorts

**Trial Contact:** Dr Pieter Koorts

**Contact Details:**
Grantley Stable Neonatal Unit  
Royal Brisbane and Women's Hospital  
Butterfield Street  
Herston Qld 4029

Tel: +61 7 3636 0563  
Fax: +61 7 3636 5259

**Trial Email:** Pieter_Koorts@health.qld.gov.au
Title: Targeted Delivery suite Intervention Study

ACTRN12609000986279

Trial Question: Would the use of volume-targeted ventilation from point of delivery until admission to the neonatal intensive care unit reduce the incidence of hypocarbia in the first 2 days of life?

Treatment Groups: Triggered volume-targeted mechanical ventilation vs standard non-triggered intermittent mandatory ventilation

Trial Status: Currently recruiting

Single Centre: Yes

Recruitment Target: 90

Recruitment as at February 2012:

Coordinating Centre: Nepean Hospital

Chief Investigator: Dr Mark Tracy

Trial Contact: Dr Mark Tracy

Contact Details:
NICU
Nepean Hospital
PO Box 63
Penrith NSW 2751

Tel: +61 4143 24162

Trial Email: Mark.tracy@swahs.health.nsw.gov.au
The CPAP Study

Title: In very preterm infants who are being extubated to nasal continuous positive airway pressure (CPAP), does a continuous positive airway pressure (CPAP) recruitment manoeuvre post extubation improve global and regional end-expiratory lung volume, thoracoabdominal asynchrony and work of breathing.

ACTRN12610000167066

Trial Question: Does continuous positive airway pressure recruitment manoeuvre post-extubation improve breathing in very preterm infants compared with no recruitment manoeuvre?

<table>
<thead>
<tr>
<th>Treatment Groups:</th>
<th>CPAP recruitment manoeuvre vs no recruitment manoeuvre</th>
</tr>
</thead>
<tbody>
<tr>
<td>Trial Status:</td>
<td>Currently recruiting</td>
</tr>
<tr>
<td>Single Centre</td>
<td>Yes</td>
</tr>
<tr>
<td>Recruitment Target:</td>
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<td>Recruitment as at February 2012:</td>
<td>11</td>
</tr>
<tr>
<td>Coordinating Centre:</td>
<td>Royal Women’s Hospital, Melbourne</td>
</tr>
</tbody>
</table>

Chief Investigators: Professor Peter Davis, Risha Bhatia

Trial Contact: Risha Bhatia

Contact Details: The Royal Women’s Hospital
Neonatal Services
Cnr Grattan St and Flemington Road
Parkville VIC 3052

Tel: +61 3 8345 3773
Fax: +61 3 8345 3789

Trial Email: risha.bhatia@thewomens.org.au
The effects of nasal continuous positive airways pressure on cardiac function in premature infants with established lung disease and premature infants with minimal lung disease

ACTRN12611001057976

**Trial Question:** In preterm infants with a corrected gestational age of 28-34 weeks, do levels of nasal CPAP of 4 or 8 cm of water affect right ventricular cardiac output?

<table>
<thead>
<tr>
<th>Treatment Groups:</th>
<th>Each infant is his/her own control as different levels of nasal CPAP are compared</th>
</tr>
</thead>
<tbody>
<tr>
<td>Trial Status:</td>
<td>Not yet recruiting</td>
</tr>
<tr>
<td>Single Centre</td>
<td>Yes</td>
</tr>
<tr>
<td>Recruitment Target:</td>
<td>68</td>
</tr>
<tr>
<td>Coordinating Centre:</td>
<td>Royal Women's Hospital VIC</td>
</tr>
</tbody>
</table>

**Chief Investigator:** Dr Sheryle Rogerson

**Trial Contact:** Dr Sheryle Rogerson

**Contact Details:**
The Women's Hospital  
Cnr Grattan Street and Flemington Road  
Parkville VIC 3052

Tel: +61 3 8345 2000

**Trial Email:**
sheryle.rogerson@thewomens.org.au
The HINT Trial:
High-flow for Infants in Non-Tertiary Centres

**Title:** High-flow nasal cannulae versus ambient oxygen for the treatment of newborn infants with early respiratory distress in non-tertiary special care nurseries: A multicentre, randomised controlled trial.

**Trial Question:** Does high flow nasal cannula reduce the number of newborn infants requiring transfer to a tertiary care centre, compared with ambient (headbox/crib) oxygen?

<table>
<thead>
<tr>
<th>Treatment Groups:</th>
<th>Ambient (headbox/crib) oxygen versus HFNC</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Trial Status:</strong></td>
<td>Not yet recruiting</td>
</tr>
<tr>
<td><strong>Multi Centre</strong></td>
<td>Yes</td>
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<tr>
<td><strong>Recruitment Target:</strong></td>
<td>520</td>
</tr>
<tr>
<td><strong>Coordinating Centre:</strong></td>
<td>Gosford Hospital and The Royal Women’s Melbourne</td>
</tr>
</tbody>
</table>

**Rationale:** HFNC use in NICUs to treat newborn infants with respiratory distress is increasing rapidly throughout the world. A recent survey found that SCNs had also begun to use HFNC despite the lack of evidence for its safety or efficacy in any setting. Due to its simplicity and potential benefits, HFNC is possibly an ideal therapy for Australian non-tertiary centres, and may overcome the problems of ‘tyranny of distance’ between regional centres and metropolitan NICUs. A high quality, well-powered, prospective trial is required in the SCN setting.

**Methods:** Multicentred trial involving approximately 8 SCNs in NSW and Victoria. The SCNs all have a paediatrician and do not currently use CPAP to treat and keep babies with respiratory distress.

**Trial Coordinator:** Assoc/Professor Adam Buckmaster

**Trial Contact:** Assoc/Professor Adam Buckmaster

**Contact Details:**
Gosford Hospital, NSCCAHS
Holden Street
Gosford NSW 2250

**Trial Email:** abuckmaster@nsccahs.health.nsw.gov.au

Tel: +61 43 202 111
TO$_2$RPIDO Study

**Title:** Targeted oxygen for the resuscitation of premature infants and their developmental outcome

ACTRN12610001059055

**Trial Question:** To demonstrate if stepwise oxygen targeting is feasible for the resuscitation of extremely premature infants.

<table>
<thead>
<tr>
<th>Treatment Groups:</th>
<th>Targeted oxygen saturation measured by pulse oximetry vs resuscitation commenced with pure oxygen followed by 10% stepwise decrements</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Trial Status:</strong></td>
<td>Currently recruiting</td>
</tr>
<tr>
<td><strong>Multi Centre</strong></td>
<td>Australia, Malaysia, Singapore, India, China, Thailand</td>
</tr>
<tr>
<td><strong>Additional Centres Needed:</strong></td>
<td>Yes</td>
</tr>
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<td><strong>Recruitment Target:</strong></td>
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<tr>
<td><strong>Recruitment as at February 2012:</strong></td>
<td>150</td>
</tr>
<tr>
<td><strong>Coordinating Centre:</strong></td>
<td>Dept of Newborn care, Royal Hospital for Women, NSW</td>
</tr>
<tr>
<td><strong>Centres Currently Recruiting:</strong></td>
<td>The Royal Hospital for Women, Randwick, NSW</td>
</tr>
</tbody>
</table>

**Chief Investigator:** Julee Oei

**Trial Contact:** Julee Oei

**Contact Details:**
Royal Hospital for Women
Baker Street
Randwick NSW 2031

Tel: +61 2 9382 6152
Fax: +61 2 9382 6191

**Trial Email:**
Ju.oei@sesiahs.health.nsw.gov.au
j.foster@usyd.edu.au

More collaborating centres needed