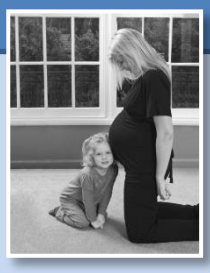
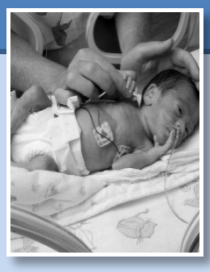
The ON TRACK Network

October 2017

Newsletter Edition 15



What's in this issue?

Welcome to the October edition of the ON TRACK Network newsletter

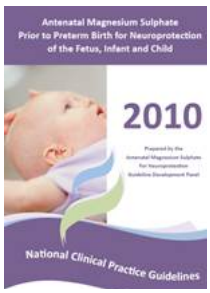
ON TRACK News

- New WHO recommendations for PPH – see over the page
- There has been a great response with concept submissions for the ON TRACK Trial Development Workshop. Put the dates in your diary and come along to hear more.
- Clinical trials save money! New publication this month shows potential savings of $290M every year MJA 2017;207(7):289-93.
- The OBLIGE Trial has commenced recruitment. Congratulations and Good Luck to Michelle Wise and her team!

Outpatient Balloon vs. Inpatient Gel
Oblige

GEMS
hPOD
HINT2
MAGENTA
MAGNUM
MBM
PAEAN
PINTO
PROVIDE
STRIDER NZAus
TARGET

The use of magnesium sulphate prior to birth <30 weeks for infant neuroprotection is recommended in bi-national guidelines and now considered standard practice. What is less clear is whether these benefits apply at later preterm gestational ages. **The MAGENTA trial is set to answer this question.**



MAGENTA aims to assess whether giving magnesium sulphate compared to placebo to women immediately prior to birth at 30 to 34 weeks gestation will reduce the risk of death or cerebral palsy (CP) in their children at two years corrected age.

Study design: A multi-centre, double-blind, placebo-controlled randomised trial.
Inclusion criteria: Women with singleton or twin pregnancy at risk of birth at 30^{+0} to 34^{+0} weeks where birth is planned or definitely expected within 24 hours.
Primary Outcome: Death or CP measured at two years corrected age
Treatment groups: IV infusion 4g magnesium sulphate OR placebo.
Sample Size: 1676 babies will be recruited to detect a decrease in combined outcome of death or CP from 9.6% to 5.4%.
New Zealand hospital recruiting sites: Auckland City, Middlemore, Christchurch Women's, Dunedin.
Recruitment to date: 1593 babies-95% of the target sample!

MAGNESIUM SULPHATE AT 30 TO 34 WEEKS' GESTATIONAL AGE: NEUROPROTECTION TRIAL

MAGENTA is so close to completing recruitment. Keep up the great work, only 83 babies to go!

Antenatal Corticosteroids Clinical Practice Guidelines.: http://www.ligginstrials.org/ANC_CPG.

Upcoming Events

ON TRACK Trial Development Workshop

19 - 20th February 2018, Liggins Institute, Auckland. Registration details will be available in the next ON TRACK newsletter.

ON TRACK & IMPACT Network - Embedding Research into Clinical Practice

24-25th March 2018. ANZ Viaduct Events Centre, Auckland. Registration open and more details http://psanz2018.com.au/

PSANZ 2018 Whenua ki Whānau

Annual PSANZ Congress **25-28th March 2018** ANZ Viaduct Events Centre, Auckland. Registration open and more details http://psanz2018.com.au/

Perinatal Society of Australia & New Zealand
Annual Scientific Congress
25 - 28 March 2018
ANZ Viaduct Events Centre, Auckland, New Zealand
Whenua ki Whānau
Nurturing the people of our land

Become a member of Perinatal Society of New Zealand &receive a discount on registration fee
http://www.perinatal.org.nz/

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The ON TRACK Network

Introducing Capital and Coast DHB-Wellington Regional Hospital

Dr Max Berry is a neonatologist in Wellington's NICU and Senior Lecturer in Paediatrics at Otago's Wellington School of Medicine, and is the local ON TRACK Site Network Leader. She kindly answered a few questions for us.

Let's understand a bit more about Wellington and Capital & Coast DHB. We are a Level 3 neonatal unit caring for around 1000 babies each year from Wellington, the Kapiti Coast and Wairarapa as well as from as far afield as Nelson and the Hawkes Bay. Many of our families have to deal with only the distress of having a sick baby, but there are often major logistical issues we need to help support them with as well.

What large multi-centre trials are you involved with? We are recruiting babies to PAEAN, HINT-2, PROVIDE and Protect.

Are you running any local studies? Yes! We have a number of studies taking place as part of our 'NIMO' series (Near Infrared Spectroscopy for Monitoring Brain Oxygenation). These look at the impact of common neonatal conditions, as well as their therapeutic interventions, on tissue oxygen levels and are being led by Maria Saito Benz, a very capable PhD student. We're also involved in trials looking at the effects of maternal probiotics on child's later health and other studies testing the effects of RSV vaccination on bronchiolitis risk and outcomes.

What are your local barriers to participation in clinical research? There is a huge drive to contribute to an active research culture, but, like many other centers, we struggle with the conflict of increased clinical workload and complexity. With the best will in the world, it's hard to make time for 'extras' like research participation.

How important do you feel research is for clinical practice? It's essential! Everything we do, and every increment in knowledge, is based on prior learning from research. Although here in NZ we currently provide excellent perinatal care, there is always more to do; research will show us how.

Top tips in research? Get out there and talk with midwifery, obstetric, nursing, surgical, physiotherapy and other colleagues to build a team. Talk to parents, families and whanau. Hearing different ideas and viewpoints is essential for ensuring that the questions we ask, and research we undertake, is relevant to our communities.

NEW

WORLD HEALTH ORGANISATION RECOMMENDATIONS In August we featured the WOMAN Trial and the use of TA for PPH. Since then the WHO has updated their recommendation and **now strongly recommend early use of intravenous tranexamic acid** (within 3 h of birth) in addition to standard care for women with clinically diagnosed PPH following vaginal birth or CS at a fixed dose of 1 g (100 mg/mL) IV at 1 mL/min (i.e. over 10 min) with a 2nd dose of 1 g IV if bleeding continues or restarts within 24 h. See ***Lancet Glob Health* 2017** Published online October 31 http://dx.doi.org/10.1016/S2214-109X(17)30428-X for details

Update Your Practice

Should we use more antibiotics for CS births in obese women?

Valent et al
JAMA 2017;318(11):1026-1034
doi:10.1001/jama.2017.10567

Obesity is the most common risk factor for surgical site infection (SSI) after CS and so as we face what seem to be ever-increasing rates of CS delivery and maternal obesity we continue to see increasing SSI. The use of a single dose of preoperative antibiotics is now standard practice for all women undergoing CS but do women with an increased BMI benefit from additional antibiotic therapy?

JAMA | Original Investigation

Effect of Post-Cesarean Delivery Oral Cephalexin and Metronidazole on Surgical Site Infection Among Obese Women
A Randomized Clinical Trial

This was a single centre randomised placebo-controlled trial including women with BMI ≥30 and undergoing CS. All participants received chlorhexidine skin preparation, 2g cefazolin IV prior to skin incision and a standardised surgical approach to CS.

Women were randomised to receive a course of oral cephalexin 500 mg and metronidazole 500 mg or placebo (total 6 doses every 8 hours for 48 hours). Randomisation was stratified by membrane status prior to delivery (intact vs ROM). The primary study outcome was development of an SSI within 30 days of delivery. SSI included superficial incisional, deep incisional, or organ/space infection and was assessed at two postoperative evaluations at two and six weeks postpartum.

Results: 403 women were included in the study, 61% had a scheduled CS. The overall rate of SSI was 10.9%. The use of a 48 hour course of prophylactic antibiotics was associated with a reduction in SSI 6.4% vs 15.4% (RR 0.41 95%CI 0.22-0.77, p=0.01). Within subgroup analysis the effect remained significant for those women with ROM; 9.5% vs 30.2% (RR 0.31 95%CI 0.1-0.7, p=0.08) but not for women with intact membranes; 5.0% vs 8.7% (RR 0.58 95%CI 0.2-1.2, p=0.47).

What does this mean? There are some limitations to this study and so we should not jump to a change in practice just yet. The study is underpowered to fully assess maternal risks with regards to allergy and other adverse effects, it does not explore infant effects and alterations to the microbiome or the implications for wider antimicrobial resistance. However, the finding particularly in women with ROM warrants further consideration and examination in future research.