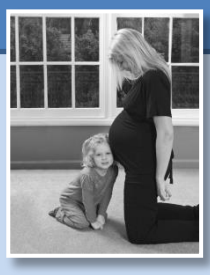
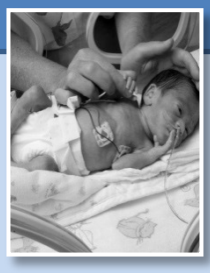
The ON TRACK Network

Sept 2016

Newsletter Edition 3



Welcome! Spring is here and so is the third edition of the ON TRACK Network Newsletter! This month we feature the hPOD trial and meet Tauranga hospital. We hope you enjoy your edition as much as this Waikato mum is enjoying her latest additions!

What's In This Issue?

ON TRACK News:

- Welcome to Amanda Rouse who has been appointed the Site Network Leader for MidCentral DHB- we are looking forward to having you on board Amanda & working with MidCentral.
- ON TRACK is hosting a **Clinical Trial Concept Development Workshop** in early 2017. This two day workshop will facilitate the development of several trial concepts aiming to answer priority research questions. A call for abstract submissions will be made shortly. Attendees may already be part of investigator groups or come along to see what is happening and have the opportunity to get involved in projects early in the development phase. The event will see internationally acclaimed speakers share their knowledge about multicentre RCT design & current funding possibilities. More details to follow in our next newsletter.
- Congratulations to the TARGET team for gaining their 500th recruit & completing over 100 follow up visits!

At Your Place - Tauranga

We talk to Site Network Leader Chris Thurnell about research activity in Tauranga

Tell us a little bit about the obstetric and perinatal services offered at Tauranga Hospital?

We are a secondary level obstetric unit with a level 2 neonatal service with 12 SCBU cots catering for over 32 week and 1500g babies. We have around 2300 deliveries a year with 7 labour rooms, & we recently opened the Women's Assessment Unit which also functions as a day stay area on the Delivery Suite.

Are there any large maternal & perinatal trials currently running?

We have only just started becoming involved with research of this calibre. We started as a site for hPOD in 2014, then MAGENTA and TARGET, all of which are still ongoing.

ON TRACK introduced at Tauranga's Perinatal Meeting

Tauranga staff recruiting to MAGENTA & hPOD

What are the research interests of staff? If they were going to run a trial, what would the topic be? *One area mentioned was understanding the evidence for best practice in the role of oximetry in weaning of respiratory support after babies are transferred from a tertiary to a secondary unit SCBU like ours.*

What do you think are the priority research questions in maternal and perinatal health? Where are the gaps in knowledge? *I think a better understanding of the feto-maternal processes that initiate normal labour would help us to understand and possibly prevent preterm labour. Additionally, I sometimes worry that induction of labour bypasses those feto-maternal processes, and may cause the baby to miss out on some pre-labour priming or development that they may be designed to trigger. Understanding these processes more fully could revolutionise the way we approach the 'when' and 'how' we deliver vulnerable babies. As a non-Paediatrician I think that fetal origins of adult disease, epigenetics and probiotics open up really interesting 'big picture' questions for the future.*

What are the barriers to participation in clinical research at Tauranga Hospital? *I don't think we regarded ourselves as a unit that had the capacity or interest to contribute to significant studies until recently. Certainly in Obstetrics, we have grown tremendously in the last 15 years from a midwife and consultant delivered service with one SHO, to a full layer of trainees and junior staff, 5th / 6th year medical students, and midwifery students.* ***I think the main barrier to clinical research is probably the mindset of staff like me that have been here a long time. The culture is changing, but at times I think we need reminding that investing in research should be part of our core role. There are huge collateral benefits to embedding research into our practice, and we have started to see improvements in engagement at all levels, knowledge, the use of evidence within the department and collaboration between the staff working in different areas.***

How could the ON TRACK Network support Tauranga in your research endeavours/interests? *We have been really well supported so far in the studies we have been part of. Queries are answered immediately, liaison visits from the trial leaders and co-ordinators for encouragement. We have had offers from academics to help us with planning or statistical help with any studies we may wish to start, and it could be useful for the ON TRACK Network to start facilitating discussion between similar sized units on how to best approach common problems and issues. Through the University, it could encourage O & G and Paediatric trainees that come on their 'rural run' to conduct studies or research in their time here.*

Chris & Tauranga Delivery Suite Team

Give us a couple of Tauranga's 'Top Research Tips'? *For recruitment, being readily available for queries is essential, so that no moment gets missed. 'Sharing the love', trying to involve all staff in recruiting, so that we don't lose a recruit just because it is 3am! For example when recruiting for MAGENTA we have somebody who has recruited before taking somebody (anybody that hasn't – LMC, DHB Midwife or doctor) along with them to see how it is done. Next time around we would hope that the new person would show another newbie how to do it. We are developing a mechanism whereby those front-line staff that are actively involved with studies are rewarded with training or study grants as a further incentive.*

Thanks to Chris and the team for talking with us and for all your efforts with research in Tauranga.

ontracknetwork@auckland.ac.nz

We thought you might be interested to find out more about the hPOD trial, now in phase two. Read on...

The ON TRACK Network

hPOD: Hypoglycaemia Prevention with Oral Dextrose Gel: the hPOD Study

Congratulations to the nine New Zealand sites recruiting for hPOD! Thank you North Shore, Waitakere, Auckland City, Auckland Birthcare, Waikato, Tauranga, Hawkes Bay, Whakatane & Southland- your efforts make a difference. Keen to join them? See info below.

Hypoglycaemia is the commonest metabolic disorder of the newborn, and the only known common preventable cause of brain damage in newborn babies. Approximately 30% of newborn (about 21 000 in New Zealand each year) are born at risk of hypoglycaemia, and require repeated blood glucose monitoring. Half of these (10 500 per year) will develop hypoglycaemia, and an unknown number will experience brain damage or developmental delay as a result. Treatment of neonatal hypoglycaemia commonly requires admission to Newborn Intensive or Special Care Units (NICU/SCBU), separating mothers and babies and interfering with the establishment of breast-feeding, thus incurring high social and financial cost.

We recently have demonstrated that ***treatment*** of neonatal hypoglycaemia with oral dextrose gel was more effective than feeding alone in reversing hypoglycaemia, and reduced both the rate of NICU admission for hypoglycaemia and the rate of formula feeding at two weeks of age. Importantly, the gel is cheap, well tolerated, simple and safe to administer, and was acceptable to families and caregivers. We now wish to determine whether oral dextrose gel is effective in ***preventing*** hypoglycaemia, and hence in preventing many of the adverse effects associated with this common problem.

Aim: To determine if oral dextrose gel, given to babies at risk of hypoglycaemia shortly after birth, will prevent neonatal hypoglycaemia and, therefore, admission to NICU/SCBU.

Method: hPOD is a multi-centre, double-blinded, randomised, placebo-controlled trial. Babies at risk of hypoglycaemia (infants of diabetic mothers, late preterm, high or low birthweight), mother planning to breastfeed & baby unlikely to require NICU/SCBU admission for other reasons are randomised to receive 40% dextrose gel or placebo gel massaged into the buccal mucosal at one hour of age. Babies are managed according to the usual hospital protocol, including blood glucose measurement at 2 hours of age and intermittently thereafter. The primary outcome is admission to NICU/SCBU; secondary outcomes include incidence of hypoglycaemia, breastfeeding rates, and costs of care before discharge. Follow-up at two years' corrected age will allow further assessment of any potential longer term benefits or adverse effects.

Research Impact: Should oral dextrose gel be effective in preventing hypoglycaemia, this would potentially:
*Reduce admissions to NICU/SCBU, avoiding the need to separate mother & baby & save millions in healthcare-related costs
*Improve breastfeeding rates, with long-term health, cognitive and social benefits
*Improve developmental outcomes by preventing hypoglycaemia-induced brain injury

Would your site like to join hPOD?
Contact hpod@auckland.ac.nz
P: 0800 004763
wwww.liggins.auckland.ac.nz/hpod

510/2129 babies recruited! Well done!

1. Harris DL, Weston PJ, Signal M, Chase JG, Harding JE. Dextrose gel for treating neonatal hypoglycaemia: A randomized placebo-controlled trial (The Sugar Babies Study). Lancet 382: 2077-83, 2013. DOI: 10.1016/S0140-6736(13)61645-1.

2 Harding, JE, Hegarty, J, Crowther, CA, Edlin, R, Gamble, G, Alsweiler, JM. Randomised trial of neonatal hypoglycaemia prevention with oral dextrose gel (hPOD): Study Protocol. BMC Pediatrics :120. 2015. DOI:10.1186/s12887-015-0440-6.

Multicentre RCTs Recruiting Near You

APTS apts@ctc.usyd.edu.au	**hPOD** hpod@auckland.ac.nz	**HINT2** k.williamson@auckland.ac.nz	**Magenta** magenta@auckland.ac.nz
Magnum magenta@auckland.ac.nz	**My Baby's Movements** mbmtrial@gmail.com	**PAEAN** paean@ctc.usyd.edu.au	**Pinto** Ruth.Hughes@cdhb.health.nz
Provide bcormack@adhb.govt.nz	**Strider NZAus** stridernzaus@auckland.ac.nz	**Target** target@auckland.ac.nz	**GEMS** gems@auckland.ac.nz

Site Network Leaders

Northland- David Bailey
Waitemata- Jutta van den Boom
Auckland- Melissa Brown
Middlemore- Michael Meyer
Waikato- Phil Weston
Tauranga- Chris Thurnell
Whakatane- Maggie Sadlier
Taranaki- Belinda Chapman
Rotorua- Anne Jaquiery
Gisborne- Sean Pocock
Whanganui- TBC
Nelson- Flora Gastrell
Palmerston North- Amanda Rouse
Grey Base- Sherif Mehrez
Hastings- Kirsten Gaerty
Christchurch- Nicola Austin
Wellington- Max Berry
Timaru- TBC
Hutt Valley & Wairarapa Chris Mallon
Dunedin- Pauline Dawson
Southland- Meggan Zsemlye

Update Your Practice: The PPROMT Trial

PPROMT was awarded the Australian Clinical Trials Alliance 2016 Trial of The Year. Read more about the recommendations for care of women with PPROM

Immediate delivery compared with expectant management after preterm pre-labour rupture of the membranes close to term (PPROMT trial): a randomised controlled trial

Jonathon M Morris, Christine L Roberts, Jennifer R Bowen, Jillian A Patterson, Diana M Bond, Charles S Algert, Jim G Thornton, Caroline A Crowther, on behalf of the PPROMT Collaboration

The research question: For women with a singleton pregnancy & PPROM at 34-37 weeks (or PPROM prior to 34w once reached 34w) does immediate delivery compared to expectant management reduce neonatal infection without increasing other morbidities.

Study design: Multicentre randomised controlled trial in 65 centres across 11 countries. Women with PPROM between 34 and 36+6 weeks and no signs of infection were randomly assigned to immediate delivery or expectant management (women with immediate delivery had delivery scheduled as close to randomisation as possible and ideally within 24 hours, for expectant management birth occurred after spontaneous labour or when the clinician caring for the woman felt it was indicated. Antibiotics were administered according to local protocols.

Primary outcome: Incidence of neonatal sepsis.

Results: The study took 10 years to complete recruitment but achieved its sample size of 1839 women.

There was NO difference in the primary outcome of neonatal sepsis: 2% immediate vs 3% expectant (RR 0.8, 95%CI 0.5-1.3)
or in a composite outcome of neonatal morbidity and mortality: 8% immediate vs 7% expectant (RR 1.2, 95%CI 0.9-1.6)

BUT immediate birth resulted in:
↑ morbidity for the neonate (RDS and need for ventilation), longer NICU/SCBU stay
↑ CS rates
↓ maternal hospital stay, APH or intra-partum haemorrhage and intra-partum fever

When reviewing these results we should also remember the increasing amount of evidence suggesting late preterm birth (34-36 weeks) is associated with long-term adverse effects through childhood and as an adult.

In a planned subgroup analysis of women with group B streptococcus there was also NO difference in the primary outcome of neonatal sepsis (RR 0·9, 95% CI 0·2–4·5).

What does this mean: In the absence of overt signs of infection or fetal compromise we should follow a policy of **EXPECTANT MANAGEMENT** for women with PPROM from 34 to 37 weeks. However, do remember that appropriate surveillance of maternal and fetal wellbeing is important and delivery may become indicated before 37 weeks is reached (e.g. evidence of infection, evidence of fetal compromise).

The full article: **Morris JM et al Lancet 2015** http://dx.doi.org/10.1016/S0140-6736(15)00724-2 and editorial comment by Knight and Churchill doi:10.1016/S0140-6736(15)00809-0

ontracknetwork@auckland.ac.nz