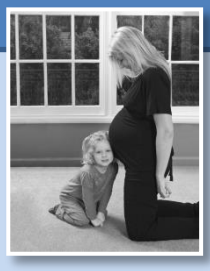
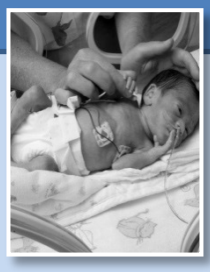
The ON TRACK Network

September 2017

Newsletter Edition 14



What's in this issue?

- ON TRACK News
- Feature Trial hPOD
- Upcoming Events
- Update your practice PROGRESS, published this month!

Welcome to the September edition of the ON TRACK Network newsletter

ON TRACK News

- The second ON TRACK Concept Development Workshop (Feb 2018) accepting concept submissions NOW
- The Australasian PROGRESS trial has been published this month (see over). Congratulations Caroline and team!
- Third cluster goes live in the My Baby's Movement (MBM) Trial. New Zealand sites go live mid-2018
- TARGET is on target to complete recruitment very soon
- Australian Placental Transfusion Study (APTS) results presented this month, publication expected next month

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

hPOD Hypoglycaemia Prevention with Oral Dextrose

Hypoglycaemia is the commonest newborn metabolic disorder, and the only preventable cause of brain damage in newborn babies. Approximately 30% of babies are born at risk of hypoglycaemia, requiring repeated blood glucose monitoring. Half of these will develop hypoglycaemia, and an unknown number will experience brain damage or developmental delay as a result. Treatment of hypoglycaemia usually requires admission to NICU/SCBU, separating mothers and babies and interfering with the establishment of breastfeeding. Oral dextrose gel is cheap, well tolerated, accepted, simple and safe to administer. **Could this be the answer?**

Previous work has shown that *treatment* of neonatal hypoglycaemia with oral dextrose gel is more effective than feeding alone in reversing hypoglycaemia, and reduces both the rate of NICU/SCBU admission for hypoglycaemia and the rate of formula feeding at two weeks of age. The pre-hPOD Trial has also shown that dextrose gel *prophylaxis* can reduce the incidence of hypoglycaemia in babies at risk by approximately 30%. **The hPOD Trial aims to determine whether oral dextrose gel can prevent neonatal hypoglycaemia and be effective in reducing NICU/SCBU admission.**

In this multi-centre, double-blind trial babies at risk of hypoglycaemia are randomised to a single dose of 40% dextrose gel or placebo gel 0.5ml/kg massaged into the buccal mucosal at one hour of age. Babies are managed according to the local hospital protocol, including blood glucose monitoring at two hours of age and intermittently thereafter.

Sites already on-board: Auckland City, Waikato, North Shore, Tauranga, Hawkes Bay, Whangarei, Southland, Whakatane and Women's & Children in Adelaide.

Inclusion Criteria: At risk of hypoglycaemia by at least ONE; mother has diabetes, birth <37 wks, SGA (<2.5kg, <10th centile or LGA (>4.5kg, >90th centile) AND all of the following; ≥35 wks, ≥2.2kg, <1hr old, no reason for NICU, planning to be breastfed

Exclusion Criteria: major congenital anomaly; had formula feed or IV fluids, hypoglycaemia, in NICU or imminent admission

If you would like to get involved with hPOD **Email** hpod@auckland.ac.nz **Call** 0800 004763 or **Text** 0221364933

Harris et al. Dextrose gel for treating neonatal hypoglycaemia: A randomized placebo-controlled trial (The Sugar Babies Study). Lancet 2013. DOI: 10.1016/S0140-6736(13)61645-1.
Hegarty et al. Oral Dextrose Gel to Prevent Neonatal Hypoglycaemia in Newborn Babies at Risk: a Randomised Controlled Dose-Finding Trial (The pre-hPOD Study). PLoS Medicine 2016 http://journals.plos.org/plosmedicine/article?id=10.1371/journal.pmed.1002155

The ON TRACK Network

Upcoming Events

ON TRACK Trial Development Workshop

Monday 19 & Tuesday 20th February 2018, Liggins Institute, Auckland.

Translating a research idea into a successful clinical trial proposal can be a daunting task. This two-day workshop will help you bring your research idea to reality. **Submission deadline Monday 6th November.** See flyer attached to the newsletter for further details. This is also a great chance to experience and join in with the development of research ideas, so even if you don't have your won concept save these dates in your diary. Registration details to follow soon.

ON TRACK & IMPACT Network - Embedding Research into Clinical Practice

The ON TRACK Network will co-host this two day meeting with the PSANZ IMPACT Network in **Auckland 24-25th March 2018**. We will explore how we can further integrate research into our everyday practice including presentations from UK guest speakers, Professors Anna David and Sara Kenyon. The meeting will include opportunity to present abstracts on the meeting theme; and proposed clinical trials and current clinical trials for which you may want input from expert IMPACT members. More details can be found https://impact.psanz.com.au/
Call for submissions will be advertised soon. Meeting registration is already open http://psanz2018.com.au/

PSANZ 2018 Whenua ki Whānau

The annual PSANZ Congress is coming to New Zealand for the first time in eight years. This is a unique opportunity. **ANZ Viaduct Events Centre, Auckland 25-28th March 2018.** The very best of NZ maternal and perinatal health research will be showcased alongside leading international and Australasian experts providing the most up-to-date evidence to guide best practice care.

This transdisciplinary meeting includes themed plenary sessions, breakfast sessions, expert sessions, research symposia, submitted oral presentations and informal poster viewing events with plenty of time for networking.

Closing date for abstract submissions & early bird registration: 10th November

For more details about this meeting and registration: 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/

Update Your Practice

Published this month

PROGRESS

Vaginal progesterone pessaries for pregnant women with a previous preterm birth to prevent neonatal respiratory distress

Crowther et al
PLoS Medicine, 2017
https://doi.org/10.1371/journal.pmed10023

Progesterone is a 'pro-pregnancy' hormone with suppressive actions on pro-labour factors. Levels of progesterone do not change as pregnancy advances but it is likely a functional withdrawal of progesterone contributes to labour initiation. Over the last 20 years a wide variety of studies have been undertaken to explore the efficacy of progesterone for the prevention of preterm birth. The PROGRESS study adds more to our understanding and is one of the few trials to include clinically relevant outcomes. Simply prolonging pregnancy does not always directly translate into health benefits.

Women were recruited in 39 hospitals including Christchurch Women's, Auckland City, Waikato, Wellington & Dunedin in this double-blind, randomised placebo-controlled trial.

Women with a singleton or twin pregnancy with a previous spontaneous preterm birth were recruited at 18-24 weeks and received 100mg vaginal progesterone or placebo until 34 weeks or birth, whichever occurred first. The primary outcome of the trial was the rate and severity of neonatal respiratory distress syndrome (RDS); a main cause of neonatal morbidity and mortality.

Results: The original sample size was based on a reduction in RDS from 15% to 9% (n=984). Independent interim analysis adjusted the required sample size to 784 women. 787 were recruited and randomised. Outcome data was available in 100% of mothers and infants.

There was **no difference in the incidence of RDS 10.5% progesterone vs 10.6% placebo** (RR 0.98, 95%CI 0.6-1.5) or in RDS severity or a composite of serious infant outcome. There was also no difference in rates of preterm birth <37 weeks (36.5% vs 37.2% RR 0.97, 95%CI 0.8-1.2).

9% of women did not start medication or forgot to use ≥3 times per week. The rates of reported side effects were high; but similar between groups 34% progesterone vs 31% placebo. Physical health, mental health, postnatal depression and anxiety scores were similar between groups.

What does this mean? Results of the PROGRESS trial do not support routine use of vaginal progesterone pessaries in women with a previous spontaneous preterm birth to reduce the risk of neonatal morbidity. However, they do appear to be safe and there *may* be some women who do benefit from progesterone (e.g. women with a short cervix) and so results of an on-going individual patient data meta-analysis are keenly awaited as this may be help identify these more specific groups.

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