ON TRACK News

ON TRACK NETWORK
BETTER HEALTH FOR MOTHERS AND BABIES
Te Awhi Rito

TOGETHER WE CAN ACHIEVE BETTER HEALTH FOR MOTHERS AND BABIES

February 2023

Welcome

Welcome to the First edition of ON TRACK News for 2023!

We welcome you back to a fresh new year, a clean slate where anything is possible, new discoveries will be made and new connections will be forged. We do hope you have had some time to unwind and relax and are now ready with renewed drive for improving the perinatal and maternal health outcomes for our Aotearoa, New Zealand to thrive in.

LATEST NEWS

C*STERIOD sites in Australia are opening.

*The first participant was recruited in Sunshine Hospital (VIC) this week. Plenty more sites will be coming on-board in the next few months including Mercy Hospital for Women (VIC), Monash Health (VIC), Royal North Shore (NSW), Royal Brisbane & Women's Hospital (QLD), The Royal Women's Hospital (VIC), St George Hospital (NSW) and Women's & Children's Hospital Adelaide (SA). If you are attending PSANZ, feel free to join the C*STEROID & PRECeDe Investigators meeting.*

The **Trans Pregnancy Care Project** has completed their perinatal workforce survey receiving almost 500 responses, WOW! The findings will come out later in the year. In the meantime you can read their peer-reviewed article published in *Women's Reproductive Health*

Congratulations to the PLUSS trial for their 1000th recruit! They only have 60 more babies to complete their enrolment.

The Protect Study has recently added Middlemore hospital to their site list, and recruited their first participant in January!

Pentoxifylline to PROTECT the preterm brain

Concepts Submissions accepted till the 20th of February. ON TRACK Network's Annual Trial Development Workshop. **5th and 6th of April 2023, Auckland.** Register

C*STEROID and PRECeDe Investigators Meeting
Date: Tuesday 7 March 2023
Time: 12:45 – 1:30pm
Place: Melbourne Convention and Exhibition Centre, Room 103
RSVP form: https://forms.gle/rd3hXGi3frEC5uUu8

IN THIS EDITION

Update Your Practice: Neurocognitive Outcomes at Age 2 Years After Neonatal Hypoglycaemia in a Cohort of Participants From the hPOD Randomized Trial.
Read more on page 2

ON TRACK Network's 7th Annual Trial Development Workshop
Read more on page 3

Feature Trial: PIPPA Tamariki -Paracetamol and Ibuprofen in Primary Prevention of Asthma
Read more on page 4

SAVE THE DATE

Perinatal Society of Australia & New Zealand Annual Congress Melbourne, 5-8th March 2023, www.psanz.co.au
NZAPEC Pre-eclampsia & Fetal Growth Study Day Auckland, 24th March 2023, www.nzapec.co.nz
ON TRACK Network Trial Development Workshop Auckland, 5-6th April 2023, www.ontrack.perinatalsociety.org.nz
International Federation of Placenta Associations meeting 2023 Rotorua, 5-8th September 2023, www.ifpa2023.org

UPDATE YOUR PRACTICE: Neurocognitive Outcomes at Age 2 Years After Neonatal Hypoglycaemia in a Cohort of Participants From the hPOD Randomized Trial.

Harding, J.E. et al, Published JAMA, October 2022.
doi:10.1001/jamanetworkopen.2022.35989

Background

Neonatal hypoglycaemia is common. We know that symptomatic or prolonged hypoglycaemia may cause brain injury and death, but we are less certain about the outcomes of brief transitional hypoglycaemia. Thus, a team of researchers examined the relationships between neonatal hypoglycaemia and neurocognitive outcomes at 2 years' corrected age in a subset of children in New Zealand who participated in a randomised trial of prophylactic oral dextrose gel.

Design

This study was an exploratory cohort analysis of the hypoglycaemia Prevention with Oral Dextrose (hPOD) multi-centre, double-blinded randomised controlled trial and its 2-year follow-up. The trial recruited 2149 late preterm and term infants born at risk of neonatal hypoglycaemia (i.e., infants of mothers with diabetes, small and large) but who were otherwise well from 18 maternity hospitals across New Zealand and Australia between January 2017 and July 2021.

Only infants randomised in New Zealand were included in this study. Infants were randomised to receive a single dose of prophylactic 40% oral dextrose or placebo gel 1 hour after birth and breastfed. Blood glucose concentrations were measured 2 hours after birth, and infants were screened and treated for hypoglycaemia according to hospital practice. Hypoglycaemia was defined as 1 or more episodes of consecutive blood glucose concentrations of < 2.6 mmol/L in the first 48 hours, recurrent as 3 or more episodes of < 2.6 mmol/L and severe as one or more episodes of < 2.0 mmol/L. Infants who experienced hypoglycaemia were treated with supplemental feeds, oral dextrose gel or intravenous dextrose. At 2 years corrected age, children underwent a neurological examination, the Bayley Scales of Infant and Toddler Development (Bayley-III) and tests of executive function. Caregivers completed questionnaires about the child's medical and family history.

The aim of the cohort analysis was to examine associations between neonatal hypoglycemia and neurocognitive outcomes at corrected age 2 years.

Primary outcome – neurosensory impairment defined as blindness, hearing impairment requiring aids, cerebral palsy, developmental delay or performance -based executive function total score more than 1.5 SD below the cohort mean.
Secondary outcomes –components of the primary outcome and their severity.

Results

Of the 1359 children recruited to the hPOD trial, 1197 (91%) were assessed at 2 years' corrected age. Three children were excluded because of unavailable blood glucose data, leaving 1194 children in the analysis. Of these, 490 (41%) children had experienced neonatal hypoglycaemia (60 [13] experienced recurrent episodes and 107 [22%] severe episodes). Those who experienced neonatal hypoglycaemia were more likely to be male, have a lower gestational age and birth weight, be a twin or born preterm, be admitted to NICU and be randomised to placebo gel.

Compared with children who did not experience hypoglycaemia, those who did were more likely to have neurosensory impairment (23% [111/487] vs 18% [125/704]; aRR, 1.28; 95% CI, 1.01-1.60), especially after severe (28% [30/106] vs 18% [125/704]; aRR, 1.68 [95% CI, 1.20-2.36]) but not recurrent episodes (19% [12/63] vs 18% [125]; aRR, 1.06; 95% CI, 0.63-1.80). Children who did and did not experience hypoglycaemia had similar risks of cognitive, language, or motor delay, but those who experienced hypoglycaemia were more likely to have lower Bayley-III cognitive and motor composite scores. There was no difference between children who did and did not experience hypoglycemia in the risk of cerebral palsy, developmental delay or poor executive function.

Conclusion

Compared with late preterm and term children born at risk of neonatal hypoglycaemia, those who experienced hypoglycaemia were more likely to have neurosensory impairment at 2 years' corrected age, especially after severe episodes.

What does this mean for New Zealand practice? The usefulness of these findings for clinical practice is limited, given the exploratory cohort design of this study. However, this study may interest clinicians and families who follow the long-standing and largely perplexing debate about the neurocognitive outcomes of milder and briefer neonatal hypoglycaemia.

ON TRACK Network's Annual Trial Development Workshop April 2023

OTN is giddy with excitement! Our 7th annual Trial Development Workshop is just around the corner and we can't wait to greet you all again for this much anticipated special event.

Concept submissions are beginning to flood our inbox so this year will surely be packed with interesting topics. If you are interested in learning about the development of clinical trials to improve the health of mothers and babies in New Zealand we encourage you to join us!

Date: 5th and 6th of April 2023
At: Clinical Education Centre, Auckland City Hospital, located at 2 Park Road, Grafton, Auckland, 1023

The workshop will include faculty experts in Māori health, health economics, biostatistics, consumer opinion, clinical trial design and funding, with opportunity for great discussions and fantastic networking opportunity that has become legendary!

This once a year golden opportunity will fast track your learning and is open to practiced researchers and students alike who are interested in developing perinatal and maternal health clinical trials and large observational studies.

REGISTRATION IS NOW OPEN!

Please click on the link HERE to register your attendance for this two day event.

Concept Submissions close on the 20th of February. Please download the application form from our website HERE

nz apec
ACTION ON PRE-ECLAMPSIA
Registered as Charitable Trust AK/684343

Pre-eclampsia & Fetal Growth Study Day

Held on - Friday 24 March 2023

At: The Maritime Room, Princes Wharf, Auckland Waterfront. Guest speakers are: Professor Katie Groom, Dr Ngaire Anderson, Professor Jason Gar-dosi, Professor Larry Chamley and Tara McNally.

To Register: https://www.nzapec.co.nz/conference

Paracetamol and Ibuprofen in Primary Prevention of Asthma:

to determine whether paracetamol compared to ibuprofen for treatment of babies with pain or fever in the first year of life increases the risk of asthma at 6 years of age.

Asthma affects thousands of children each year who often go on to have life-long asthma and other allergic conditions. Despite the many advances in the management of asthma, the number of children with asthma in New Zealand remains very high. Paracetamol and ibuprofen are safe and effective for relieving pain and fever in babies, but previous observational studies suggest that their use may influence the chance of developing asthma. PIPPA Tamariki will find out if rates of asthma at 6 years of age are different in children who take only paracetamol for pain or fever in their first 12 months, compared to children who take only ibuprofen during this time.

Secondary outcomes include eczema and atopy at 3 years and 6 years, and bronchiolitis at 1 year.

To be eligible, babies must be born in New Zealand; be aged less than 8 weeks; be born at more than 32 weeks gestation; have not been given any paracetamol or ibuprofen (excluding via mother's breast milk); expect to live in NZ for their first 6 years

December 2022: 88% recruited. 3494 of the required 3922 babies have been enrolled so far.

Website: www.pippatamariki.ac.nz

Facebook: PIPPA Tamariki

Sites: Wellington and Hutt: 027 2920705; pippatamariki@mrinz.ac.nz

Middlemore: 021 897982; pippatamariki@auckland.ac.nz

Auckland and the rest of New Zealand: 021 02063156; pippatamariki@adhb.govt.nz

The trial is a collaboration between Auckland, Counties Manukau, Waitematā, Capital & Coast and Hutt District Health Boards, and Auckland, Otago, Massey and Calgary Universities and the Medical Research Institute of New Zealand.

New Zealand Trials		New Zealand recruits
PROTECT Me	Antenatal melatonin supplementation in fetal growth restriction for fetal neuroprotection	22
C*STEROID	Corticosteroids before planned caesarean section from 35^{+0} to 39^{+6} weeks of pregnancy	432
FIIX Trial	The Fertility, IVF and Intrauterine Insemination trial in couples with unexplained infertility	544
NeoGluco	Neonatal Glucose Care Optimisation Study (I)	73
PIPPA TAMARIKI	Paracetamol and Ibuprofen in Primary Prevention of Asthma	3547
PLUSS	Preventing Chronic Lung Disease in Extremely Preterm Infants Using Surfactant + Steroid	211
PROTECT	IV pentoxifylline as adjunct therapy to improve long-term disability in preterm infants	105
Recruitment Completed - follow up to primary outcome and/or data analysis ongoing		
MAGENTA	Magnesium Sulphate at 30 to 34 weeks' gestational age: Neuroprotection Trial	
DIAMOND	Different Approaches to Moderate & later preterm Nutrition	
Childhood Outcome Studies		
GEMS Follow up study	Gestational Diabetes Mellitus Trial of Diagnostic Detection Threshold	
TARGET Follow up study	Optimal glycaemic targets for women with gestational diabetes: the randomised trial	
ProViDE 6-8YR Follow up study	Higher IV protein intake for extremely low birthweight babies in the first week after birth on survival free from neurodevelopmental disability at 2 years' corrected age	
hPOD@6-8YR Follow up study	Hypoglycaemia Prevention in newborns with Oral Dextrose	