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

MARCH 2021

Welcome

Welcome to the March edition of ON TRACK News

Kia ora, this month we catch up with one of our concept lead investigators from our Trial Development Workshop that took place in February and we feature the C*STEROID Trial currently recruiting women across a number of New Zealand sites. If you have any feedback, or would like to share any of your maternal and perinatal clinical trials news, please do get in touch.

LATEST TRIALS NEWS

Middlemore Hospital recruit their 50th baby into the PLUSS Trial

With just over 400 babies recruited into the **PLUSS Trial** across 15 NICUs in New Zealand and Australia, the team at Counties Manukau District Health Board are definitely punching above their weight with the recruitment of their 50th baby. Well done to the team at Middlemore Hospital!

C*STEROID Trial is off to a great start at Auckland City Hospital

The **C*STEROID Trial** is now open at **Auckland City, Christchurch, Tauranga** and **Waikato** hospitals. Being the first site to open, **Auckland City** have now recruited their 100th participant thanks to the hard work and dedication of the team (pictured). Congratulations to **Christchurch** who have started recruitment this month. You can read more about the C*STEROID trial on page 2. Pictured left to right: Sarah Graham, Rebecca Hay, Mariska Oaks-ter Bals, Laura Mackay, Katie Groom

SAVE THE DATE

PSANZ Annual Congress (Virtual) 29-31 Mar 2021 - https://www.psanz.com.au/

RANZCOG 2021 NZ Annual Scientific Meeting Wellington - 21 - 22 Jun 2021 - https://www.nzasm.org.nz/

New Zealand College of Midwives 16th Biennial National Conference - Christchurch - 5-6 Nov 2021 - https://www.midwife.org.nz

PSNZ 72nd Annual Scientific Meeting 2021 - Rotorua - 2-5 Nov 2021 - https://www.paediatrics.org.nz/

Survive to thrive: Feeding NZ's preterm babies better 15 Apr 2021 Liggins Institute **public lecture and webinar** Auckland & Virtual REGISTER NOW https://www.auckland.ac.nz/en/liggins.html

IN THIS EDITION

NEW Site Network Leaders!

Read about the latest developments with new Site Network Leaders appointed at four sites nationwide **page 3**

Trial Development Workshop 2021

We had a great time during our workshop and from the feedback received it seems you did too! We provide an update on one of the concepts on **page 3**

C*STEROID Trial

Our featured trial is C*STEROID. Find out how your site can join and learn about the great resources available on **page 2**

C*STEROID Funders:

cure kids
Hugo Charitable Trust
Lottery Grants Board Te Puna Tahua LOTTO FUNDS FOR YOUR COMMUNITY
hrc nz

Featured Trial: Corticosteroids before planned caesarean section from 35^{+0} to 39^{+6} weeks

C*STEROID

THE AIMS OF C*STEROID AT A GLANCE

A multi-centre placebo-controlled randomised trial, to assess the effects of corticosteroids prior to planned caesarean section at **35^{+0} to 39^{+6} weeks** on neonatal health.

It is designed with sufficient power to assess both **neonatal benefit and harm** to reliably inform future clinical practice.

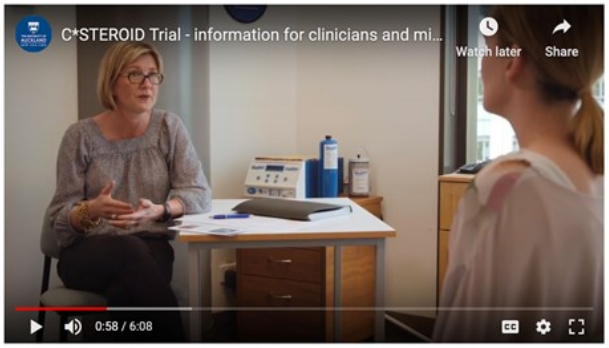
This trial will also establish a randomised cohort of sufficient size to be able to assess the **childhood benefits and/or harm** of this intervention.

Background Following completion of the C*STEROID Feasibility Study (June 2019 to March 2020) which recruited 88 mothers and 92 babies from Auckland City, Tauranga and Waikato hospitals, the C*STEROID Trial commenced on the 5th October 2020. Over 2,500 pregnant women and their babies will be recruited into the trial, which is the largest undertaken in this area of research and the first to explore both the benefits and potential side-effects of corticosteroids given to pregnant women undergoing planned caesarean section (CS) from 35^{+0} to 39^{+6} weeks gestation. The trial is now being rolled out across the ON TRACK Network and is open to recruitment at Auckland City, Christchurch, Tauranga, and Waikato hospitals, with further sites currently going through the research approvals process.

About the trial The intervention is betamethasone or placebo injection given intramuscularly as two doses 24 hours apart within 7 days of planned CS. The primary outcomes of the trial are:

- Co-primary outcome (neonatal benefit): **incidence of respiratory distress** requiring >60 minutes of respiratory support.
- Co-primary outcome (neonatal harm): **incidence of hypoglycaemia** (blood glucose level <2.6 mmol/L) prior to primary hospital discharge.

The trial is open to any sites across New Zealand where women undergo planned CS at 35^{+0} to 39^{+6} weeks gestation.



How to have that first conversation about the trial:
www.liggins.auckland.ac.nz/csteroid

Women are eligible for recruitment if they meet the following **inclusion criteria:**

- **Planned pre-labour CS ≥35^{+0} to 39^{+6} weeks gestation**
- ≥24 hours* and <7 days until planned birth
- **Singleton or twin pregnancy with a live fetus**

**to allow two doses of study drug to be administered at 24 hours (+/- 4 hours) apart, prior to the planned CS.*

Women are not eligible to take part if they have diabetes (pre-existing or gestational), have received IM corticosteroids in the current pregnancy, or if they were previously involved in the C*STEROID Feasibility Study or C*STEROID Trial.

After birth babies' blood glucose concentration is measured using an i-STAT or blood gas machine for at least 12 hours with treatment if hypoglycaemia (<2.6mmol/L) occurs. The trial also involves data collection from clinical notes to time of hospital discharge (mum and baby) and six-week questionnaires via email (maternal infection, breastfeeding, EPDS, SF-36).

The Auckland based research team will maintain contact with families and are planning to undertake childhood outcome studies at 6-7 years to assess impact on neurodevelopment, executive function, body size, and respiratory, cardiovascular and metabolic wellbeing subject to further funding.

Interested in your site becoming involved? Sites that become involved have thorough training and are offered excellent support from the lead site in Auckland. Some great resources are also available to sites including a webinar, i-STAT training video, study participant information sheets in multiple languages, e-consent and site specific lanyards.

If you are interested in learning more about the trial and potentially joining recruitment, please look at the trial's resources available online and use the contact details provided.

Sign post potential participants to :
www.liggins.auckland.ac.nz/csteroid
www.facebook.com/csteroidtrial

FOR FURTHER INFORMATION:

Email	csteroid@auckland.ac.nz
Website	www.liggins.auckland.ac.nz/csteroid
Facebook	www.facebook.com/csteroidtrial

ON TRACK Network Trial Development Workshop Concept Update

The ON TRACK Network hosts annual Trial Development Workshops designed to help develop clinical trial concepts in maternal and perinatal health to a level suitable for competitive grant funding. Our fifth workshop took place in Auckland last month. Dr Charlotte Oyston, Senior Lecturer, University of Auckland and Obstetrician, Middlemore Hospital was one of the Concept Lead Investigators to bring her trial proposal to our latest Workshop. Here is what she said about her experience.

"The concept I brought to the ON TRACK Workshop was **a clinical trial of early monitoring and treatment versus standard antenatal care for prediabetes in early pregnancy.**

All women in New Zealand have an HbA1C (blood glucose test) at booking as part of their routine antenatal screen. The reason for this test is to detect women with pre-existing diabetes. By doing this test, we have identified a group of women whose HbA1c suggests their blood sugars have been higher than normal, but are below the threshold for diagnosing diabetes. These women are considered to have pre-diabetes. A study at our unit, as well as other research in New Zealand, and overseas, have shown that these pregnancies are at increased risk of preterm birth, preeclampsia, and perinatal death. There is, however, a lack of evidence to suggest that glycaemic testing and treatment of these women in the early stage of pregnancy improves maternal or perinatal outcomes. This has led to variation in the management of prediabetes in pregnancy across New Zealand.

During the Workshop the concept was discussed and reinvented in a multidisciplinary group with representatives from across New Zealand. The group included midwives, clinicians, experienced researchers, a biostatistician, and Māori health and consumer representatives. Hearing the differences in approach to the treatment of prediabetes from different perspectives was really important for considering how we might design the study to make it work as a multi-centre trial. We also gained a study acronym – "ACCEPT" ACessing Care Early for Pre-diabeTes, which is always pleasing!

In terms of next steps, we have recognised the need to undertake more networking and feasibility work, including a survey of different DHBs current approaches to the treatment of prediabetes in pregnancy, and the potential willingness of units across New Zealand to participate as recruiting sites. Once we have this information, we will design a small pilot/feasibility study to refine the study design.

The workshop was an incredibly useful experience, those involved in the group, and the mock review panel gave feedback that was constructive and supportive, as well as challenging! Overall, I have come away with a sense of direction, and feeling more excited about research in this area."

Charlotte pictured standing third from right

The Site Network Leader baton is passed on for Rotorua, Wairarapa, Waikato and Taranaki

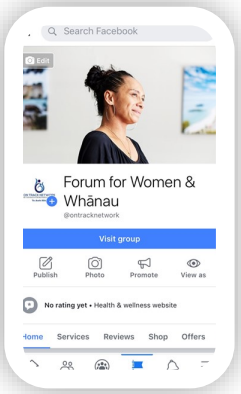
Everyone across the Network plays a crucial role in helping to achieve better health for mothers and babies through much needed clinical trials research. A particularly important role is the **Site Network Leader (SNL)**. SNLs are the 'enablers' for all units to become more actively involved in clinical trials research. They act as the local champions, providing the crucial link between the central national Network and local clinical trials activities.

SNLs are senior practitioners with an interest in research who advocate for the ON TRACK Network within their hospital and disseminate information about the Network and our activities. They provide liaison between the Network and local clinical services, providing feedback from their hospital to the Network. They work with Site Network Coordinators who assist with the ON TRACK Network activities and maybe directly involved with delivery of clinical trials locally.

We value these roles hugely and recognise the hard work and dedication of those who take on the SNL role. On occasion the baton must be passed on and we are delighted to welcome four new SNLs to the team, taking over the excellent work of their predecessors. Welcome **Emma Deverall** (Rotorua), **Jill Arliss** (Wairarapa), **Richard Foon** (Waikato) and **Olivia Payne** (Taranaki). We very much look forward to having you on board and making great things happen!

If you are interested in learning more about these important and rewarding roles please contact us for more information (ontracknetwork@auckland.ac.nz).

Forum for Women & Whānau



The **Forum for Women & Whānau** aims to engage with consumers of mothers and babies health to improve their understanding of clinical trials research and engage them to be involved in clinical trials research across the whole pipeline.

The Forum showcases clinical trials and shares stories from trial participants to inspire others to get involved. It informs people of various Network supported projects, facilitating collaboration between consumers and clinicians/researchers, for example, our recent Research Prioritisation Project, and annual Trial Development Workshops.

Growing the Forum is one of the Network's key objectives for 2021, getting more people involved with its activities who are directly impacted by the clinical trials research the Network supports. Our aim is to have a nationwide diverse and inclusive Forum reflective of the backgrounds, experience, and ethnicity of New Zealanders.

The Forum predominantly uses Facebook as its platform for consumers to interact, comment, engage and contribute to the Network's activities. Anyone can join the Forum and we simply ask members is to contribute what they can when they can to clinical trials discussions and activities. Quarterly newsletters are also distributed in whānau rooms and clinic waiting areas to encourage people to join us on Facebook but to also allow those not using social media the opportunity to join specific projects within the Network.

If you know of anyone who might be interested in joining the Forum, please direct them to our Facebook page (**www.facebook.com/ontracknetwork**) and remember we have posters and flyers that we can send you to help advertise this great initiative locally at your site, just contact us via email for your supply.

New Zealand Trials		New Zealand recruits
Protect Me	Antenatal melatonin supplementation in fetal growth restriction for fetal neuroprotection	2
C*STEROID	Corticosteroids before planned caesarean section from 35^{+0} to 39^{+6} weeks of pregnancy	142
DIAMOND	DIfferent Approaches to MOderate & late preterm Nutrition	403
FIIX Trial	The Fertility, IVF and Intrauterine Insemination trial in couples with uneXplained infertility	240
Little Eye Drop	Phenylephrine and Cyclopentolate Eye Drops in Neonates	92
NeoGluco	Neonatal Glucose Care Optimisation Study (I)	29
OBLIGE	Comparing two methods of starting an induction of labour in pregnant women (balloon at home versus hormone gel in hospital) to assess chance of vaginal birth	975
PAEAN	Preventing Adverse Outcomes of Neonatal Hypoxic Ischaemic Encephalopathy with Erythropoietin	69
PIPPA	Paracetamol and Ibuprofen in Primary Prevention of Asthma	2044
PLUSS	Preventing Chronic Lung Disease in Extremely Preterm Infants Using Surfactant + Steroid	84
PROTECT	IV pentoxifylline as adjunct therapy to improve long-term disability in preterm infants	41

Recruitment completed - follow up to primary outcome ongoing	
C*STEROID Feasibility	C*STEROID Feasibility: Corticosteroids before planned CS form 35^{+0} to 39^{+6} weeks
ECOBABe	The ECOBABe study (Early Colonisation with Bacteria After Birth)
GEMS	Gestational Diabetes Mellitus Trial of Diagnostic Detection Threshold
MAGENTA	Magnesium Sulphate at 30 to 34 weeks' gestational age: Neuroprotection Trial
PROVIDE	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

Childhood outcome studies	
hPOD@2YR Follow-up Study	Hypoglycaemia Prevention in newborns with Oral Dextrose
TARGET Follow up Study	Optimal glycaemic targets for women with gestational diabetes: the randomised trial