

ON TRACK

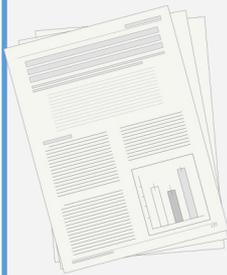
Welcome to our May ON TRACK Network newsletter

ON TRACK News



We are seeking **representation for Māori** on the Network's National Executive Committee (NEC). This role will contribute to all the work of the NEC but with particular focus on how the Network can engage more closely and support wāhine Māori, pēpi and their whānau. If you are interested in learning more about this opportunity, please email us:

ontracknetwork@auckland.ac.nz



Have you or colleagues had any **publications** or received any **research grants** in women's and babies' health that relate to clinical trial activity supported by the Network? If so, please share details with us for our next ON TRACK Strategic Research Initiative Fund (SRIF) report. The report provides essential information for our funders. It is also a great opportunity to collectively demonstrate the collective hard work of clinical trials research in New Zealand and can be used to support our sustainability beyond the SRIF funding. Please email details to us: ontracknetwork@auckland.ac.nz



We have taken advantage of the lock down to update our **website** including more content about Network activities and a new section for women and whānau. We would love to receive your feedback in making this a valuable resource for everyone. <http://ontrack.perinatalsociety.org.nz/>

Kia ora. Welcome to the May edition of ON TRACK News. This month we continue to monitor the COVID-19 situation, but we would also like to acknowledge that 5th May was **International Midwives Day**, 12th May is **International Day of the Nurse** and 20th May is **International Clinical Trials Day**. Amidst the challenges of the current pandemic it's still important to take time to **acknowledge the fabulous work of our midwives, our nurses and all those delivering much needed research** during this time—**thank you!**

The ON TRACK Network Research Prioritisation Project

What questions about the health of New Zealand mothers and babies would you like to see answered by research?



We are conducting a national study to identify and prioritise the research most urgently needed to improve health and healthcare for mothers and babies in New Zealand. The first step in this project is to **collect current knowledge gaps** from a large and diverse group of people across New Zealand including women and whānau, healthcare professionals and other stakeholders (e.g. scientists, researchers, funders, policy-makers). Once knowledge gaps have been identified, research questions that can fill those gaps will be developed. These research questions will then be considered by a diverse and representative Ranking Group using predetermined and weighted criteria of answerability, effectiveness, deliverability, potential to reduce disease burden and impact on equity. At the end we will have the **Top Ten Research Priorities for Mothers and Babies Health in New Zealand**.

We need to hear from you

The project will only be a success if we get the right information in at the start and this means **we all need to contribute**. It's really simple to. Just complete an **on-line questionnaire** or contact us for a **video or phone interview**. You can access the on-line questionnaire here:

<http://bit.ly/ontrack2020>

For a video/phone interview contact: Clara Mossinger, midwife and PhD student, Liggins Institute, University of Auckland. She will arrange a time convenient for you: c.mossinger@auckland.ac.nz or 022 4311 988.

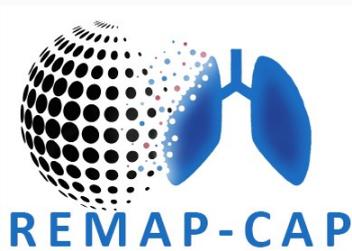
This project provides a chance for the whole of New Zealand to determine what mothers and babies research we should do in the future. Whether you are a clinician or a researcher (or both!) this is your opportunity to push your own agenda! Furthermore, if you spend 15-20 minutes contributing your thoughts you will also be in with the chance to win one of ten \$25 prezy cards.



New Zealand's urgent response to the need for COVID-19 related clinical trials

Pandemics are unpredictable and emerge suddenly posing a significant challenge to clinician researchers wanting to investigate best management and treatment. **The COVID-19 pandemic has highlighted the importance of effective and inclusive clinical trials infrastructure for New Zealand to get urgent research off the ground quickly and efficiently.**

Acknowledging the immediate need for clinical trials evidence to inform best clinical care for patients with COVID-19, last month the Health Research Council of New Zealand (HRC) issued an urgent funding call. As a result of that call three New Zealand clinical trials into potential COVID-19 treatments were funded to help combat the current coronavirus outbreak. Two of the trials will investigate treatment for patients admitted to hospital with COVID-19, the third will investigate the use of hydroxychloroquine for prophylaxis in front-line healthcare workers. Of the three trials, a trial named REMAP-CAP may potentially recruit pregnant and postpartum women.



REMAP-CAP: Randomized, Embedded, Multifactorial Adaptive Platform trial for Community-Acquired Pneumonia (CAP). This trial is an extension of an international trial that has been recruiting in New Zealand over the previous 3 years. It is supported by the Australian and New Zealand Intensive Care Society Clinical Trials Group (ANZICS CTG).

This adaptive trial is designed to determine and continuously update the optimal set of treatments for CAP over time. Its REMAP design allows participants to be randomised to receive one intervention in each of one or more categories of treatment ("domains").

These interventions can be tested simultaneously. Treatments being investigated (open label) include: antiviral therapy; corticosteroid treatment strategy; and immune modulation.

Interestingly, REMAP trials are designed with a pandemic like COVID-19 in mind because in the event of a novel or re-emerging respiratory pathogen, REMAP trials can evaluate the most relevant treatment options. In fact, this trial has been designed by clinicians who cared for patients and conducted research during the 2009 H1N1 pandemic. There will be a lot to learn not just from the results of this trial but how it is conducted, hopefully we may be able to consider platform trials in the future for maternal and perinatal health.

REMAP-CAP has now recruited 352 participants with suspected or proven COVID-19 infection and the trial has COVID-19 treatment domains being added in accordance with the trial's adaptive design. <https://www.remapcap.org/>



UK COVID-19 related clinical trial recruiting pregnant women

As yet, no drugs are of proven value for COVID-19 although there are several which may be helpful (or possibly harmful) when added to standard supportive care. The UK **RECOVERY Trial** aims to examine some of these additional treatments and pregnant women may be included.

The trial is recruiting those who are in hospital with confirmed COVID-19. Treatments being investigated are: Lopinavir-Ritonavir (commonly used to treat HIV); corticosteroids; hydroxychloroquine (a treatment for malaria); azithromycin (a commonly used antibiotic); and for those patients whose condition is more severe, tocilizumab (a treatment for rheumatoid arthritis). The RECOVERY trial has 173 recruiting sites and 8,949 participants. Results will have implications for treatment of COVID-19 globally. <https://www.recoverytrial.net/>

New Zealand maternal and perinatal clinical trials coming soon There are three new trials in maternal and perinatal health we expect to open to recruitment in New Zealand sites once the national COVID-19 alert status permits and ethics and regulatory approvals are in place. Keep an eye on the clinical trials page of our website to learn more.

The NeoGluCO Study: Diazoxide for babies with severe or recurrent low blood glucose: The Neonatal Glucose Care Optimisation Study.

The PROTECT Me Trial: Assessing antenatal maternal melatonin supplementation in fetal growth restriction to improve neurodevelopmental outcomes.

The C*STEROID Trial: Corticosteroids before planned caesarean section ≥ 35 weeks.





COVID-19 surveillance and research during pregnancy

Global clinical research related to the current pandemic is largely focussed on treatments for patients admitted to hospital with COVID-19 and those known to be particularly vulnerable i.e. the elderly and those with underlying health conditions. However, given the gaps in knowledge about COVID-19 and its effect on pregnant women and their babies, it is important to at least implement surveillance of COVID-19 during pregnancy to inform the best management of this potentially vulnerable group too.

We know that during pregnancy women experience immunological and physiological changes that could potentially make them more susceptible to viral respiratory infections such as those caused by coronaviruses. Adverse pregnancy outcomes have been observed from severe acute respiratory syndrome (SARS) and Middle East respiratory syndrome (MERS) (Rasmussen 2020; WHO 2020). However, little data on the effect of COVID-19 in pregnancy are currently available.

Studies published to date indicate pregnant women with COVID-19 might not be at increased risk for severe complications or adverse reproductive health outcomes, but those studies are limited to case series and case reports and lack sufficient numbers to determine uncommon risks attributable to COVID-19 infection (Chen 2020). Reports concerning vertical transmission are also inconclusive (Mullins 2020; Dong 2020; Zhu 2020). This emphasises the importance of COVID-19 surveillance in pregnancy and there have now been a number of registries set up internationally, at least eight of them on our last count. Two studies of interest are our own New Zealand registry and a UK surveillance study investigating mother-to-child transmission:

New Zealand COVID-19 in Pregnancy Registry. This registry study is awaiting ethics approval but should be live within the next few weeks. It is planned to include all women in New Zealand who are pregnant and up to six weeks after birth who have been diagnosed with COVID-19. The Registry aims to include women at all gestations of pregnancy cared for in the community, and in hospital. Routinely collected information regarding the mother's health, current pregnancy and birth, and newborn health and COVID-19 status will be included. It is hoped the system developed will be fit for purpose in future epidemics/pandemics and effective collection of national data on rare conditions in pregnancy. For further information [email: covid19@auckland.ac.nz](mailto:covid19@auckland.ac.nz) website: www.liggins.auckland.ac.nz/covid19

Peri-COVID: understanding COVID-19 infection in pregnant women and their babies has been designed in the UK with the primary objective to assess the risk of COVID-19 infection in newborn infants born to pregnant women with confirmed COVID-19 infection and to determine possible routes of mother-to-child transmission. This surveillance study will recruit pregnant woman with confirmed COVID-19 infection from 24 weeks gestation in England. By collecting sequential samples from pregnant women with confirmed coronavirus disease and, after childbirth, from the newborn infant, the researchers hope to better understand the risk and mode of perinatal transmission to develop an evidence base for recommendations, guidance and policy decisions for the clinical and public health management of pregnant women, their infants and the healthcare staff that care for them. <https://www.pericovid.com/investigator-information>

Join the ON TRACK Network in celebrating International Clinical Trials Day 2020!

We had planned morning teas up and down the country to celebrate **International Clinical Trials Day on 20th May**, but with the COVID-19 pandemic scuppering those plans we thought you may like to get involved from home. So, to celebrate clinical trials research this year we are having some fun with a short online quiz with a **\$50 prezzy card up for grabs!**

International Clinical Trials Day is an opportunity to recognise everyone's contribution to clinical trials.

With **7,170 participants** randomised to clinical trials currently supported by the Network it is an opportunity for us to say **"thanks!"** to all those helping to improve health and wellbeing of New Zealand mothers and babies.

To join in our celebration and for a chance to win the prezzy card, all you have to do is take part in our short online quiz. Your contact email will then be entered into our prize draw on Monday 25th May 2020.

Access the quiz [here](#) - Good luck!

Hint: if you need any help with answers, visit our website.



New Zealand Trials		New Zealand recruits
DIAMOND	Different Approaches to MOderate & late preterm Nutrition	318
FIIX Trial	The Fertility, IVF and Intrauterine Insemination trial in couples with unEXplained infertility	62
LATTE Dosage	The most effective and best tolerated dose of caffeine to reduce intermittent hypoxaemia	90
Little Eye Drop	Microdrop Administration of Phenylephrine and Cyclopentolate Eye Drops in Neonates	30
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	765
PAEAN	Preventing Adverse Outcomes of Neonatal Hypoxic Ischaemic Encephalopathy with Erythropoietin	59
PIPPA	Paracetamol and Ibuprofen in Primary Prevention of Asthma	1487
PLUSS	Preventing Chronic Lung Disease in Extremely Preterm Infants Using Surfactant + Steroid	49
PROTECT	IV pentoxifylline as adjunct therapy to improve long-term disability in preterm infants	24
Recruitment completed - follow up to primary outcome ongoing		
C*STEROID	C*STEROID Feasibility: Corticosteroids before planned CS from 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	
STRIDER NZAus Childhood Outcome Study	Sildenafil TheRapy In Dismal prognosis Early onset fetal growth Restriction (2-3 years)	
TARGET Follow up Study	Optimal glycaemic targets for women with gestational diabetes: the randomised trial	

New Zealand Clinical Trials & COVID-19



Alert Status 3

As we continue to move through different levels of COVID-19 Alert Status here is an update on recruitment status for New Zealand's multicentre maternal and perinatal clinical trials:

- **DIAMOND** recruitment remains on hold until the New Zealand Alert Level drops to at least Level 2.
- **FIIX Trial** recruitment is recommencing as fertility clinics open up and deliver services again.
- **LATTE Dosage** has re-started with selective recruitment, including babies who are expected to be in-patients for at least two weeks.
- **Little Eye Drop Study** remains on hold in Wellington, Dunedin and Invercargill. Christchurch are recommencing recruitment.
- **OBLIGE** recruitment can now re-start. Participating sites will need to contact and gain approval from their own DHB research office prior to re-starting, and the coordinating team will communicate with local teams at each site to guide them through the process.
- **PAEAN** advise sites to follow local site/health district policy, and if permitted, to continue recruitment and follow up.
- **PIPPA Tamariki** recruitment remains on hold until the Alert Level drops to 2.
- **PLUSS** recruitment continues at Middlemore and Auckland City Hospitals.
- **PROTECT** trial recruitment is continuing where possible, although some units have suspended recruitment.

