

The ON TRACK Network

May 2017

Newsletter
Edition 10



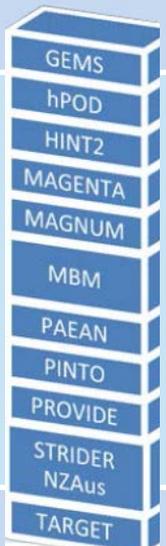
What's in this issue?

- [ON TRACK News](#)
- [Trial Development Workshop](#)
- [Profile of Kelly Thompson](#), ON TRACK Executive Committee member
- [Upcoming events](#)
- [Update your practice](#)
Meta-analysis of cervical ripening methods for IOL

Welcome to the May edition of the ON TRACK Network newsletter

ON TRACK News

This month we report on another of the trial concepts that was developed at the February workshop. Since the workshop the team have secured ethics approval and funding, and plan to start recruiting soon. We also profile our hard working consumer rep on the Executive Committee, Kelly Thompson, and present the results from a recent meta-analysis published in BJOG. Don't forget 'upcoming events', great chance for a mini-break in Sydney or Wellington!



 Maternal & Perinatal Research Coordinating Hub
Research Hub

Are you involved in the set-up, execution and completion of clinical trials?

The Research Hub at the University of Auckland is here to help all clinical trial researchers across the country and specifically to support the activity of the ON TRACK Network.

We have a range of data management services including web randomisation, database & CRF design, data entry & validation, and archiving. Check out the Hub Wiki based at the University of Auckland to access a wealth of information and resources.

<https://wiki.auckland.ac.nz/researchhub>

The ON TRACK Trial Development Workshop This month we summarise another of the concepts from our February meeting.

Induction of Labour (IOL) Trial Proposal – Dr Michelle Wise led a team of researchers from the Universities of Auckland and Otago developing a trial comparing two different methods of induction of labour.

At the moment most women in NZ have an IOL by vaginal prostaglandins in a process that often takes several days and requires them to remain in hospital. Previous trials have shown that there are fewer complications when cervical ripening is done with a balloon instead of prostaglandins and other trials show the feasibility of initiating IOL as an outpatient. However, there is a pressing need for a **large trial studying safety and effectiveness of an alternative approach to this common intervention - outpatient balloon induction.**

The research team used the ON TRACK Concept Development Workshop to fine-tune their protocol. They now have HDEC multi-site ethics approval, ANZCTR registration and very recently were awarded funding from Health Research Council and A+ Trust. This randomised controlled trial is almost ready to start recruitment with seven New Zealand hospitals committed to participating. It is expected that a total of 3 195 women will need to be included to detect the proposed reduction in CS rate.

Inclusion: low-risk women with singleton cephalic presentation planning induction \geq 37 weeks.

Randomisation to one of two protocols: (1) intervention: outpatient Foley balloon catheter (2) control: inpatient prostaglandin gel.

Primary outcome: rate of CS delivery.

Secondary outcomes include: measures of maternal and fetal morbidity, maternal satisfaction, and cost-effectiveness.

If you are interested in participating in this trial, as a midwife, O&G registrar, or maternity unit leader, please contact Dr Michelle Wise (m.wise@auckland.ac.nz).

ontracknetwork@auckland.ac.nz



The ON TRACK Network



Introducing Kelly Thompson, Consumer representative, ON TRACK Executive Committee



Can you tell us a bit about your background? My first exposure to the NICU environment came in 2008 after the early arrival of my eldest child at 24 weeks gestation. This journey, plus two subsequent high risk pregnancies under the MFM team compelled me to support other families who find themselves in similar situations by joining The Neonatal Trust Auckland. The Neonatal Trust Auckland allows us to provide support to other families who find themselves in similar situations by providing practical advice & emotional support to help them through their own neonatal journeys.

What interested you in being part of the ON TRACK Network National Executive Committee? When you have been through your own personal experience you can often provide a unique perspective. My interest is enhancing research programmes and raising awareness in the community of the benefits of participating in clinical trials.

In your opinion, how does the ON TRACK Network give value to national research in maternal and perinatal health? The ON TRACK Network offers a fantastic collaboration which ensures that knowledge & resources can be shared, and therefore enhancing overall progress.

How do you see the role of 'consumers' in research development? Consumer input is invaluable in the planning and conduct of clinical trials research. There are many aspects where we can provide a 'consumer' perspective on relevant issues including recruitment, patient information, new trials protocols and ethical issues.

Thanks so much Kelly – your commitment to the ON TRACK Network is awesome. So many of our researchers commented on how valuable it was to have you at the Workshop and your input to all our work is really appreciated. **Kelly is working with the team to develop our website which we hope to be launching very soon!**

Upcoming Events

PSANZ IMPACT Network are hosting a **Concept Development Workshop** in Sydney 2-3 August. This would be a great opportunity to observe the process of multicentre trial development or you may be interested in joining one of the investigator teams!

PSNZ 37th Annual Scientific Meeting
14th June Te Papa, Wellington



Several members of the ON TRACK Network National Executive Committee will be at the meeting – we hope to see you there!



<https://impact.psanz.com.au/meetings-and-events/impact-network-workshops/>

<https://www.perinatal.org.nz/event/37th-annual-scientific-meeting/>

Update Your Practice

Double-balloon catheter versus prostaglandin E₂ for cervical ripening and labour induction: a systematic review and meta-analysis of randomised controlled trials

YM Du, LY Zhu, LN Cui, BH Jin, JL Ou

BJOG 2017;124:891–899

Induction of labour (IOL) is increasingly common, both globally and in New Zealand. Locally, the induction rate has risen from 19% in 2005 to 24% in 2014.

Cervical ripening is the first step in the induction process, but there is uncertainty about which is the best method. This **meta-analysis** examines several large randomised trials comparing two different methods of cervical ripening.

Objective: To compare the efficacy and safety of the double balloon catheter with prostaglandin E₂ agents used for labour induction.

Methods: The team searched electronic sources including MEDLINE and the Cochrane Library. Randomised controlled trials comparing PGE₂ agents with double-balloon catheter for cervical ripening (as part of IOL) were included in the analysis. The main outcomes included the vaginal delivery rate within 24 hours and rate of caesarean section delivery. **Results:** Nine studies (1866 patients) were included in this systematic review. Both groups (PGE₂ and balloon catheter) were comparable with regard to rate of caesarean section (RR 0.92; 95% CI 0.79, 1.07), vaginal delivery within 24 hours (RR 0.95; 95% CI 0.78, 1.16) and maternal adverse events, but the risk of excessive uterine activity (RR 10.02; 95% CI 3.99, 25.17) and need for neonatal intensive care unit admissions (RR 1.31; 95% CI 1.01, 1.69) were significantly increased in women who received PGE₂ agents.

What does this mean? The two methods have similar efficacy in regards to mode of birth. However the balloon catheter is more cost effective and has fewer adverse outcomes. **What method do you use in your institution?** Maybe your institute could become involved in the NZ wide trial proposed over the page – outpatient balloon IOL vs in-patient PGE₂. This meta-analysis certainly provides some reassurance about safety and effectiveness of the balloon IOL process.