

The ON TRACK Network

August 2018

Edition 24



Welcome to the August edition of the ON TRACK Network newsletter

ON TRACK News

- ❖ Great work on the **PROVIDE trial**; recruitment is nearly complete. Just a few more to go so please keep recruiting until the research team are in touch.
- ❖ The **PLUSS trial** (a randomised controlled trial of surfactant plus budesonide to improve survival free of bronchopulmonary dysplasia in extremely preterm infants) is getting underway at Middlemore Hospital and will be coming to other NZ sites soon, read more in next month's newsletter.

ProV:De

PLUS+

Update Your Practice

Grobman et al N Engl J Med 2018;379:513-23
DOI: 10.1056/NEJMoa1800566

The NEW ENGLAND
JOURNAL of MEDICINE

Is it better to plan labour by induction (IOL) at 39-40 weeks or wait for spontaneous labour? Observational studies have compared outcomes after IOL to those of spontaneous labour and suggested there maybe no benefit for the infant and increased risk, including caesarean section (CS), for the mother.

But this comparison is not the correct one as we cannot be certain that not performing IOL will result in spontaneous labour. A more appropriate comparison is IOL vs expectant management and this is what the investigators in the US MFMU Network have set out to compare in the ARRIVE trial published earlier this month.

Results: Of 50 581 women screened, 22 533 were eligible and 6106 women agreed to participate. The trial required 6000 women to be included to have sufficient power to demonstrate that IOL was associated with a 40% reduction in the primary perinatal outcome, estimated to be 3.5% for those managed expectantly (allowing for 7.5% cross-over, i.e. not all women were expected to receive the plan allocated to them). The primary perinatal outcome was 4.3% in the IOL group and 5.4% in the expectant management group RR 0.80, 95%CI 0.64-1.00, p=0.049. Women undergoing IOL delivered at an earlier median gestational age (39.3 vs 40.0 weeks p<0.001) with a lower median birthweight (3300g vs 3380g p<0.001). The rate of birth by CS was significantly lower for the IOL group (18.6% vs. 22.2%; relative risk, 0.84; 95% CI 0.76 - 0.93; p<0.001). These women were also less likely to experience hypertensive disease, complications at CS and pain.

What does this mean in NZ: This trial cohort does not reflect NZ practice (only 6% mid-wifery led care) so should not direct us to change our standard timing of IOL. Indeed subsequent ACOG opinion does not recommend practice change but suggests it is 'reasonable' to offer IOL at 39 weeks; it also highlights the need to consider women's preferences, resources available and the setting where IOL will occur. However, this trial does suggest that a policy of avoiding IOL at 39 weeks to reduce CS rates is not valid.

We still have questions to answer about IOL in NZ—the OBLIGE trial provides the perfect opportunity for you and your unit to help answer some of these questions—see over to learn more and how to get involved!

The ARRIVE Trial: Labor Induction versus Expectant Management in Low-Risk Nulliparous Women

A randomised trial at 41 hospitals in the United States. Women considered low risk in their first pregnancy were invited to participate after 34 weeks and then randomised at 38⁺⁰ to 38⁺⁶ weeks to IOL at 39⁺⁰ to 39⁺⁴ weeks or to expectant management (elective delivery after 40⁺⁵ but no later than 42⁺² weeks). The primary outcome was a composite of perinatal death or severe neonatal complications including need for respiratory support after birth, Apgar≤3 at 5 mins, HIE, seizure, infections, meconium aspiration and birth trauma. The main secondary outcome was CS birth.

	No. of Patients	No. with Outcome	Relative Risk (95% CI)
Primary Perinatal Outcome	6096	296	0.80 (0.64-1.00)
Cesarean Delivery	6096	1243	0.84 (0.76-0.93)

Outpatient Balloon vs. Inpatient Gel

oblige



The ON TRACK Network



Multicentre Trials currently recruiting in NZ

DIAMOND

GEMS

HINT2

hPOD

MBM

OBLIGE

PAEAN

PIPPA Tamariki

PLUSS

PROVIDE

Outpatient Balloon vs. Inpatient Gel



The OBLIGE Trial. Outpatient Balloon vs Inpatient Gel for induction of labour (IOL): a multi-centre randomised trial.

In New Zealand one in four of all pregnant women have labour induced. This is usually initiated with vaginal prostaglandin gel but due to the risk of hyper-stimulation this requires on-going assessment in hospital. Many trials show that initiating IOL with a balloon has less risk and is as effective at achieving a vaginal birth. Small trials show that initiating IOL out of hospital is feasible and acceptable, and women are satisfied

with this method. Outpatient care may also be of benefit to a busy women's health service in terms of staff, beds, and overall costs. However, low-risk women are not yet offered the option of having a balloon and spending the first part of their IOL out of hospital. Outpatient IOL with balloon compared to standard care has not yet been adequately studied for effectiveness and safety.

The aim of the OBLIGE trial is to compare the effect of outpatient balloon and inpatient vaginal prostaglandin gel for IOL initiation on the rate of caesarean section in low risk women having IOL at term. Secondary outcomes include other maternal outcomes and satisfaction, neonatal outcomes, staff satisfaction and cost-effectiveness.

Current recruiting sites: Auckland City, Hawkes Bay, Nelson, Taranaki, Tauranga, Waikato, Wellington, Whakatane.

Other interested sites: Waitemata, Southern, Hutt Valley.

Inclusion criteria: Women planning IOL \geq 37 weeks with single normally-grown baby, willing and able to remain within one hour of hospital.

Lead Investigator: Dr Michelle Wise 021 302 978

Email: oblige.study@auckland.ac.nz

Facebook: OBLIGE Pregnant Mums NZ

End August: 174 of 1552 participants recruited

If you are already an active site consider ways you can increase local recruitment to the trial. If not yet involved why not give Michelle a call and see if you can be!

Dates for your diaries

The 3rd ON TRACK Concept Development Workshop, Auckland 21st and 22nd Feb 2019

Whether you would like to present a trial concept or join in with developing research ideas, we hope you will book this into your diary. More details to come from us in the coming months.



PSANZ IMPACT Network 1st and 2nd November 2018 *Enhancing Clinical Trials Activity Across the IMPACT Network.* For more details go to <https://impact.psanz.com.au/>

PSNZ Annual Scientific Meeting, Wellington 29th and 30th Nov 2018 *Joining the Dots: Journey from Antenatal through to Neonatal Care.* For more details go to <https://perinatalociety.org.nz/>



ACTA Summit, Sydney 29th and 30th Nov 2018. *Building a self-improving health care system* For more details go to <http://www.clinicaltrialsalliance.org.au>

PSANZ Annual Congress 17th to 20th March 2019 *Surfing the Waves of Evidence.*

For more details go to <http://psanz2019.com.au/>

PSANZ IMPACT Pre-congress Meeting 16th and 17th March 2019



ontracknetwork@auckland.ac.nz

<http://ontrack.perinatal.org.nz/>