

The ON TRACK Network

Dec 2016



Newsletter
Edition 6



Welcome to the December edition of the ON TRACK Network newsletter. Thank you for your support this year as the Network has been launched across the country. We hope you have been enthused about maternal & perinatal health research as ON TRACK has become established in your area & that the newsletters have provided useful & interesting reading. We wish you a safe & Happy Christmas & we look forward to working alongside you again in the New Year.

What's In This Issue?

OTN Workshop Update

Feature Trial: The PROVIDE Study

Update Your Practice: The HIPSTER Trial

Talking with a family

The OTN Concept Development Workshop 20 & 21st Feb 2017

BOOK YOUR LEAVE NOW! Our Trial Concept Development Workshop is rapidly approaching & registrations are open. Several promising research proposals have been submitted and we have world class facilitators to assist in their further development. **This is an event not to be missed.**

The concepts for development span all disciplines in maternal and perinatal health, with themes including induction of labour, antenatal corticosteroids, intra-partum syntocinon, diabetes care, caffeine for late preterm infants & interventions for reducing postnatal depression.

Almost all trial concepts have the potential to be developed & integrated into both level two & three hospitals nationwide so we encourage all practitioners & researchers from around the country to attend & be part of these trials from the concept development stage.

Registration is essential for attendance but free of charge. To register please visit <https://uoaevents.eventsair.com/on-track/on-track> or see the attached flyer for more details. We look forward to working with you to see exciting new research trials developed in NZ.

The ProVIDe study is currently running in six neonatal units around NZ. ProVIDe aims to identify how increasing protein intake in extremely low birthweight babies affects their growth, metabolic & neurodevelopmental outcomes.

The ProVIDe Study

Extremely preterm babies (birthweight between 500-1000g) often experience poor growth in the weeks immediately after birth followed by a period of accelerated growth, a pattern associated with long-lasting metabolic & neurodevelopmental effects. A key to improving the long term health of these vulnerable babies may be to avoid this pattern of growth by improving early nutritional intake. Previous research suggests increasing the protein intake of these babies is likely to be particularly important in achieving this.

This randomised control trial compares whether an extra 1 gram of protein per day for the first 5 days after birth is beneficial in improving survival free of neurodisability at 2 years of age, improving body composition & preventing faltering growth at hospital discharge compared to standard nutrition.

All participating babies will receive normal neonatal intensive care and IV nutrition in accordance with established NICU guidelines in each centre. The control group will receive a 0.45% saline solution via the umbilical artery catheter (UAC) according to current clinical practice. The intervention group will receive a UAC amino acid solution providing ~1g- 2g/Kg.d protein.

Inclusion criteria: Babies born <1000g at birth in whom a clinical decision to place an umbilical arterial catheter has been made & whose parents have given informed consent.

Exclusion criteria: Admission to NICU more than 24 hours after birth, known chromosomal or genetic abnormality, congenital disorder affecting growth, inborn error of metabolism or danger of imminent death.

If shown to be successful, implementing this simple intervention into NZ neonatal units could improve the lifelong health of babies throughout the country. To find out more about ProVIDe, contact Barbara Cormack at bcormack@adhb.govt.nz

The ON TRACK Network

What does this mean?

Update Your Practice

The HIPSTER

Trial was published this year in the New England Journal of Medicine. This trial compared high-flow therapy with CPAP as the primary respiratory therapy for preterm babies with respiratory distress (RD). The findings have important implications for practice, read on for more....

Nasal High-Flow Therapy for Primary Respiratory Support in Preterm Infants

Calum T. Roberts, M.B., Ch.B., Louise S. Owen, M.D., Brett J. Manley, Ph.D., Dag H. Froiland, Ph.D., Susan M. Donath, M.A., Kim M. Dalziel, Ph.D., Margo A. Pritchard, Ph.D., David W. Cartwright, M.B., B.S., Clare L. Collins, M.D., Atul Malhotra, M.D., and Peter G. Davis, M.D., for the HIPSTER Trial Investigators*

Unlike infants in post-extubation therapy trials, no infants in the HIPSTER study received surfactant before randomisation. The higher rate of treatment failure with high flow in the HIPSTER study may reflect its reduced effectiveness in infants with surfactant deficient lungs. Although high-flow does provide some distending pressure, the higher, more consistent pressures produced during CPAP may account for the difference in treatment failure rates.

Nasal high-flow therapy has similar efficacy to continuous positive airway pressure (CPAP) when used as postextubation treatment in neonates. The HIPSTER Trial, an international, multicentre, randomized, non-inferiority trial, aimed to establish how high-flow therapy compared with CPAP as the primary means of respiratory support for preterm infants (gestation ≥ 28 weeks) with early respiratory distress.

Eligibility criteria included, birth between 28-36+6 weeks gestation, <24 hours old, no previous endotracheal ventilation or surfactant treatment & decision by attending clinician to commence or continue non-invasive respiratory support. Exclusion criteria included urgent need for intubation & ventilation, known major congenital abnormality, pneumothorax, babies who already met the criteria for treatment failure or had already received ≥ 4 hours CPAP. 564 babies took part and were randomised to treatment with either nasal high-flow therapy or nasal CPAP.

The primary outcome was treatment failure <72 hours after randomisation. If high-flow failed, neonates could receive rescue CPAP. Neonates in whom CPAP failed were intubated & ventilated.

Recruitment stopped early (after 75% of the target sample had been recruited) at the recommendation of the independent data & safety monitoring committee because of a significant difference in primary outcome between treatment groups. Treatment failure occurred in 71 of 278 infants (25.5%) in the high-flow group & in 38 of 286 infants (13.3%) in the CPAP group. The rate of intubation & risk of adverse events did not differ significantly between groups. **When used as primary support for preterm infants with RD, high flow therapy resulted in a significantly higher rate of treatment failure than did CPAP.**

Read the full article here: <http://www.neim.org/doi/full/10.1056/NEJMoa1603694>

When considering clinical applications, please note the HIPSTER study population was limited to preterm infants in NICU environments. Further research is required to ascertain the safety & efficacy of these therapies in the non-tertiary environment, resource-limited settings & in term infants.

When considering the initial management for treating respiratory distress in preterm infants who have not been previously intubated or received surfactant, the results of this study suggest CPAP is less likely to result in treatment failure & thus should be considered preferable to high-flow in the management of these babies.



Multicentre Clinical Trials Recruiting Now!

APTS

GEMS

hPOD

HINT2

MAGENTA

MAGNUM

My Baby's Movements

PAEAN

PINTO

PROVIDE

STRIDER

TARGET

Can you tell us a bit about your pregnancy experience and the complications you faced that brought you in to hospital?

I had pre-eclampsia and a DCDA twin pregnancy. The Doppler scans showed one of the babies had low blood flow.

Did you receive any interventions as a result of this? How did you feel about these?

I had steroids before delivery, antihypertensives, twice weekly scans and frequent blood tests. I felt assured that the babies and I would be fine due to the regular monitoring I received.

Talking With A Family This Christmas

Did you participate in any clinical research during your experience? If so, how did you feel about it and why did you take part?

I participated in the MAGENTA Trial. This is a randomised controlled trial of magnesium before delivery for births at 30-34 weeks to see if it reduces the risk of babies developing cerebral palsy (CP). I knew there were benefits identified from previous studies (24-30 weeks). I wanted reassurance that I was doing all I could to reduce the risk of my babies developing CP & other learning problems. I also participated because I think research improves healthcare management & pregnancy outcomes.



Would you consider participation in research in the future and why?

Yes, to assist with improvement of maternal & early child healthcare & management.

What would you say to the health professionals currently completing/considering involvement in clinical research? Do you think research should be a routine part of our practice?

You are doing a great job of seeking better ways to look after women and their babies by seeking scientific evidence in well controlled settings.

Yes I do think it should be adopted as part of practice as health is becoming increasingly complex & management must continually evolve & improve to meet the demands & improve patients' quality of life & outcomes.

How will you be spending Christmas this year?

In NICU! Hopefully with some time for family too.

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