WHO CAN TAKE PART?

We would like to invite you to take part in the Latte study for late preterm babies!

- Do you have a baby who was born 4 to 6 weeks early and is less than 72 hours old?
- Are you planning on living in Auckland for the next 6 weeks?
- Would you be happy to be visited at home by one of our research midwives or nurses once your baby is discharged?

If you have answered yes to these questions please consider joining the Latte Dosage Trial!

WHY IS THIS STUDY HAPPENING?

Late preterm infants (4 to 6 weeks early) are the most common of all preterm infants, making up 6% of all births or 3,700 births every year in New Zealand. Most late preterm babies will have good outcomes. However, compared with term babies, they are at increased risk of cerebral palsy and delayed development. We do not know why late preterm babies have this increased risk, but it may be because they have more frequent episodes of low oxygen levels compared to term babies. Studies have shown that very preterm babies (more than 8 weeks early) who have more frequent periods of low oxygen levels are more likely to have problems with brain development.

In very preterm babies (more than 8 weeks early), caffeine is often used to help regulate breathing and prevent periods of low oxygen levels. Caffeine is very safe and has been shown to improve brain development in very preterm babies, reducing the risk of cerebral palsy and movement difficulties.

We believe that caffeine treatment may also help late preterm babies to prevent periods of low oxygen levels and improve brain development. As late preterm babies are more mature they may need a larger dose of caffeine.

The purpose of this study is to find out the best dose of caffeine to help reduce episodes of low oxygen levels in late preterm babies.

WHAT DOES THE STUDY INVOLVE FOR MY BABY?

Your baby will be randomly assigned to one of four different doses of caffeine (5mg/kg, 10mg/kg, 15mg/kg or 20mg/kg) or water, and will start having this on day three of age. Your baby will receive the study medicine every morning until the date they were expected to be born (due date). We will also ask you to complete a daily diary of the study medicine your baby has been given.

To determine the effects of the study medicine, we will also complete the following tests:

- **Pulse oximetry:** your baby will have a pulse oximetry test at day 2-3 of age, 2 weeks later and when they were expected to be born. This involves a sensor being wrapped around your baby’s foot and will measure baby’s blood oxygen levels overnight.
- **Saliva samples:** when your baby is 2 weeks of age, we would like to collect a saliva sample by wiping a cotton swab around your baby’s mouth. At the same time, we will also ask mum for a few saliva samples (provided by spitting into a tube).
- **Growth:** we will measure your baby’s weight at 2 weeks of age and on your baby’s due date.
- **Questionnaires:** we will ask you to complete questionnaires about how your baby is feeding and sleeping at 2 weeks of age and again on your baby’s due date. When your baby is 2 weeks of age, we will also ask you to complete questionnaires about yourself, how you are feeling and how many foods and drinks containing caffeine you consume.
- **Health information:** we would like to collect some general health information about your pregnancy and birth from your health records.

If you have been discharged home a research health professional will visit you at home to perform these tests.

WHAT ARE THE BENEFITS AND RISKS FOR MY BABY?

This study may benefit your baby if caffeine treatment in late preterm babies is found to reduce brain damage, but this is not yet known.

Other benefits:

- Have regular contact with a research team during your baby’s first 6 weeks that includes doctors, midwives and nurses.
Help other babies and children by contributing to medical research.

We do not expect there to be any significant risk for your baby as medical caffeine has been used safely in very preterm babies (more than 8 weeks early) for over 30 years. Occasionally babies may develop reflux (spitting up milk), irritability, poor sleeping, slower weight gain or a faster heart rate.

Thank you for your interest in the Latte Dosage Trial!

We look forward to you taking part in the Latte trial by:

- Contacting the Latte research team about enrolling or if you have any questions
- Discussing the Latte trial with your partner, whanau/family and friends
- Discussing the Latte trial with your health care provider

This trial has been funded by a feasibility grant by the Health Research Council of New Zealand.

This trial has received ethics approval from the Health and Disability Ethics Committee (HDEC) and from the District Health Board Research Committee.

HDEC reference: 18/NTA/129

Latte Trial Investigators:
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