❖ 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?
- Would you be able to give your baby medicine each day until when they were expected to be born?
- Are you happy to bring your child back for a follow up assessment at 2.5 years?

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

LATTE

❖ 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.

The purpose of this study is to find out if caffeine improves the developmental outcomes of children as they grow.

❖ WHAT DOES THE STUDY INVOLVE FOR MY BABY?

Your baby will be randomly assigned to either caffeine or an identical placebo (identical appearing medicine with no caffeine), 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). Neither you nor the study team will know if your baby is receiving the caffeine or placebo.

There will be approximately 500 babies in Aotearoa participating in the study.

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

- Heart rate: One week after study enrolment, a member of the study team will check your baby's heart rate.
- Growth: We will ask for your baby's weight, length and head circumference at 3 weeks and when your baby was expected to be born. We will also ask if your baby is breastfeeding.
- Health information: we would like to collect some general health information about your pregnancy and birth from your health records.

When your baby is discharged home you will be given 2 bottles of medication. When your baby is 3 weeks old we will arrange a courier to collect the first bottle from you and you will start using the second bottle with a new dose based on your baby's weight.

❖ WHAT ARE THE BENEFITS AND RISKS FOR MY BABY?

This study may benefit your baby if you are allocated to the caffeine treatment as it may 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 heartrate.

You will receive a Koha (gift) at enrolment and at the 2.5 year assessment, food and a $50 voucher.

Thank you for your interest in the Latte 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, whānau/family and friends
- Discussing the Latte trial with your health care provider

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

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

HDEC reference: 2022 FULL 13147

Latte Trial Investigators:

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WHERE CAN I FIND OUT MORE?

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THE LATTE TRIAL

Caffeine to improve neurodevelopmental outcomes in babies born late preterm. (A randomised controlled trial)

LATTE

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