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This study has received ethical approval from the Health and Disability Ethics Committee, reference 20/NTB/137

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PROTECT me

A randomised controlled trial of antenatal melatonin supplementation in Fetal Growth Restriction for fetal neuroprotection

The PROTECT Me Trial

What is the purpose of this study?

Fetal Growth Restriction (FGR) is a condition where baby does not grow at the rate that would be expected during pregnancy. There are many causes of FGR, but the most common cause is because the placenta (whenua) is not working as well as it should. This may result in the baby receiving lower levels of oxygen ('oxidative stress'), which may be harmful to the baby's developing brain. Currently there are no treatments available to minimise or prevent this stress on the developing brain of an FGR baby during pregnancy.

Melatonin

Melatonin is a naturally occurring hormone in the human body. It is an anti-oxidant that may be able to protect the FGR baby's developing brain from low oxygen levels ('oxidative stress'). While this is the first large trial of melatonin for fetal neuroprotection in FGR, melatonin has been used safely in previous trials in pregnancy.

Can mum taking a **melatonin** supplement during pregnancy when baby has fetal growth restriction **protect baby's brain** and lead to improved learning and development in childhood?

Is this study suitable for me?

This study may be suitable for you if:

- you are 23-31^{+6} weeks pregnant with a single baby, and
- your baby has been identified as having FGR (abdominal circumference ≤3rd centile OR ≤10th centile with one or more abnormal Doppler).

What is involved?

Participation in this study is voluntary. If you are interested in taking part you will be provided a Participant Information Sheet & Consent Form to read. If you agree:

<u>During pregnancy you will:</u>

- receive either melatonin tablets or a matching placebo to be taken three times a day until your baby is born (neither you nor your doctors/midwives will know which you are receiving).
- have blood tests at least four times during the trial period to check your full blood count, liver and kidney function.
- have a fortnightly assessment including an ultrasound scan. It is likely that these will be done even if you do not take part in the trial.

<u>After your baby/child is born they will:</u>

- have a general movement assessment around their due date and again at 3 months of age.
- have a developmental assessment around 2.5 years of age. This may be part of routine care for any babies born very early or very small.

We will collect information about you and your baby during pregnancy and after birth.

Who is organising this research?

This project is led by researchers from Monash Health and Monash University, Melbourne. It is being conducted in hospitals across New Zealand and Australia. Funding has been provided by a number of 'public good' funders including: Monash University, The Cerebral Palsy Alliance and the National Health and Medical Research Council (NHMRC), Australia.

Questions?

If you agree to take part we will tell your GP and LMC that you are taking part in the study. You may wish to discuss this study with your LMC, a friend, family or whānau support person.
If you have any questions about this study you can contact us (details on next page).