## Contact us

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If you require Māori cultural support, talk to your whānau in the first instance. Alternatively, you may contact the administrator for He Kamaka Waiora (Māori Health Team) by telephoning 09 486 8324 ext 2324.

Te Whatu Ora Health New Zealand Te Toka Tumai Auckland | Starship Child Health

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Te Whatu Ora
Health New Zealand

# Can we offer better treatments for newborn seizures?

# The **NEOLEV3** Study

# Introduction

You and your baby are invited to take part in a study aiming to find better treatments for newborn (neonatal) seizures. Your baby has been asked to take part because they are having seizures or at risk of having seizures.

We monitor and treat seizures to protect baby's brain from harm.

The current medications used to treat seizures are called phenobarbital (PHB) and phenytoin. They are good at stopping seizures but they can cause some unwanted side effects such as:

- sleepiness (sedation)
- low blood pressure
- slowed breathing (respiratory suppression)

There is also some information to suggest they may damage brain cells. They do not stop seizures for all babies with seizures continuing for around 25-40% of newborns.

There is a great need to find better medications for newborn seizures and that is what we aim to find out in this study.

# Levetiracetam treatment

Levetiracetam (LEV) is a medicine that is commonly used for older children and adults; it is safe and effective when used this way. We have less information about whether it is safe and effective for newborns. We recently completed the NEOLEV2 study which treated babies with either 60mg/kg LEV or the standard treatment, PHB. This showed that LEV was *safer* than PHB (fewer side effects) but *less effective* (seizures stopped for 28% vs 80%).

# The NEOLEV3 Study

In NEOLEV3 we want to find out if higher doses of LEV could be more effective at stopping seizures and provide safer care for babies. Your family's participation will help us to do this.

All babies in NEOLEV3 will be treated initially with LEV alone. If seizures continue babies will then receive either LEV at a higher dose or phenobarbital.

# What is involved?

Participation in this study is voluntary (your choice). If you are interested in learning more, you will be provided a Participant Information Sheet & Consent Form to read.

All babies taking part in this study will have continuous video electroencephalogram (EEG) monitoring to record electrical activity in the brain. This is similar to the standard monitoring that would occur as part of your baby's routine care.

If the EEG confirms that seizures are occurring treatment will be started using LEV at the standard dose of 60mg/kg. If there are no further seizures your baby will continue to receive LEV for 5 days.

If more seizures are seen on EEG during your baby's monitoring your baby will then be randomly assigned (by chance by a computer) to receive either:

- Additional LEV at a higher dose, or
- PHB

This study is open label, which means you and your healthcare providers will know which treatment your baby is receiving. Treatment will continue for at least 5 days.

Sometimes it may be necessary for babies assigned to LEV treatment to switch over to PHB, or for PHB to be added. This may happen if your baby's seizures increase and changing to, or adding, PHB is considered to be the safest course of treatment.

Your baby will be monitored carefully. This will include regular review of their wellbeing and blood tests at the start of treatment, 24 hours and 5 days. Most of this care is standard but some may be additional as part of the study.

Information will be collected about your child's health and wellbeing during their time in hospital. We would also like to record any follow up assessments that happen in early childhood up until the age of five.

There are additional, optional parts of the study you will be invited to consider which are described further in the full participant information sheet.

# Questions?

You may wish to discuss this study with a healthcare provider, a friend, family or whānau. If you have any questions about this study you can contact us.

This study is supported by your local hospital and has received ethical approval from the Southern Health and Disability Ethics Committee, reference *2022 FULL 13712*. It has been organised by doctors from Starship Hospital and University of Minnesota, USA. The study has a grant from the US Food and Drug Administration (FDA).