❖ WHO CAN TAKE PART?

We would like to invite you to take part in the NeoGluCO Study for babies with low blood sugar.

The **NeoGluCO Study** is looking at better ways to treat babies with low blood sugar so that they spend less time in the neonatal unit and can resume feeding more quickly.

Your baby can join the **NeoGluCO Study** if they:

- ❖ Were born at 35 weeks or greater.
- ❖ Are less than 8 days old.
- ❖ Require admission to the neonatal unit due to low blood sugar.

If this is your baby, please consider joining the NeoGluCO Study!

❖ WHY IS THIS STUDY HAPPENING?

Low blood sugar is very common in babies, affecting at least 15% of all newborns. Detecting and treating low blood sugar is important because sugar (glucose) is the main source of energy for the newborn brain. If the blood sugar remains low for too long, it may have long lasting effects on brain development.

The main risks for babies developing low blood sugar are being too small, too large, preterm (before 37 weeks) or if a mother has diabetes.

If low blood sugar episodes are severe or continue despite being given sugar (dextrose) gel in baby's mouth and/or extra milk, babies are usually admitted to the neonatal unit for intravenous dextrose via a drip.

- ❖ For babies that need admission, it can be difficult to control the sugar levels, even after starting a drip.
- ❖ For some babies it can take many days or weeks until blood sugar levels become stable and full feeding is tolerated. This is usually because baby is producing too much insulin. Insulin is a hormone that lowers the blood sugar.

The NeoGluCO Study will determine if the early use of a medicine called diazoxide in babies with severe or recurrent low blood sugar helps prevent further episodes and allows them to return to feeding more quickly and spend less time in the neonatal unit.

Diazoxide is a medicine that helps controls the rate that insulin is released. It is a **well-established** medicine that has been used for many decades in infants with other forms of low blood sugar.

WHAT DOES THE STUDY INVOLVE FOR MY BABY?

During this study, your baby will continue to receive normal medical care. However, you have the choice for your baby to be randomly assigned to receive additional diazoxide or an identical volume of placebo (no medicine). The study medicine will ideally be started as soon as possible after you have provided consent. Your baby will receive the study medicine by mouth or via their gastric tube every twelve hours until their blood sugar levels have stabilised. In most cases we expect that the medicine will be stopped after several days.

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

- ❖ **Sugar monitoring**: This is part of standard care for babies with low blood sugar. A blood test is obtained from either a heel prick or vein. Babies in the study will continue the usual sugar monitoring
- ❖ **Continuous sugar monitoring**: We will insert a tiny soft, flexible monitor under baby's skin on the thigh. The aim of the continuous monitor is to improve detection of low blood sugar while minimising the number of blood tests required. These monitors are well tolerated by babies.
- ❖ **Blood test**: We will collect a single blood sample 36 hours after starting the study medicine. Where possible, this will be timed with routine blood tests.
- ❖ **Health information**: We will collect some general health information about your pregnancy and baby's birth from your health records.

NEO GLU C O
Neonatal Glucose Care Optimisation Study

❖ WHAT ARE THE BENEFITS FOR MY BABY?

This study may benefit your baby if diazoxide treatment is found to prevent further episodes of low blood sugar. This may allow intravenous fluids to be stopped sooner, feeding to be established more quickly and for earlier discharge. There may be benefits for the brain and later development; but this is not yet known.

Other benefits:

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

WHAT ARE THE RISKS FOR MY BABY?

We do not expect there to be any significant risk for your baby as diazoxide has been used safely in babies with other medical conditions in the past. Rarely babies may start breathing fast from too much fluid or have a high blood sugar level. These problems are resolved quickly by stopping the diazoxide.

Thank you for your interest in the NeoGluCO Study!

We look forward to you taking part in the NeoGluCO Study.

- Please discuss the NeoGluCO Study with your partner, whānau/family, and health care provider.
- Please contact the NeoGluCO research team about enrolling or if you have any questions.

This study has received approval from the Health and Disability Ethics Committee (HDEC) and from the District Health Board Research Committees.
HDEC reference: 19/CEN/189

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NeoGluCO Study Investigators:

Dr Chris McKinlay (Principal Investigator, Site Investigator Middlemore Hospital), Dr Jane Alsweiler (Site Principal Investigator, Auckland City Hospital), Prof Jane Harding (Neonatologist), Prof Wayne Cutfield (Endocrinologist), Don Laing (Researcher), Jenny Rogers (Kaiarahi), Greg Gamble (Statistician), Prof Geoff Chase (Engineer), Dr Sara Hanning (Pharmacist), Michael Myer (Neonatologist), Julena Ardern (Nurse Practitioner), Lisa Mravicich (Study Coordinator).

WHERE CAN I FIND OUT MORE INFORMATION?

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A Study to Optimise Care of Babies Admitted with Low Blood Glucose

PARENT BROCHURE

Study phone: 021897982