You are invited to take part in a study aimed at improving treatment for babies with low blood glucose. Whether your baby takes part is your choice. If you don’t want your baby to take part, you don’t have to give a reason, and it won’t affect the care your baby receives. If you do want your baby to take part now, but change your mind later, you can take your baby out of the study at any time.

This Participant Information Sheet will help you decide if you’d like your baby to take part. It sets out why we are doing the study, what your baby’s participation would involve, what the benefits and risks to your baby might be, and what would happen after the study ends. We will go through this information with you and answer any questions you may have. Before you decide you may want to talk about the study with other people, such as family, whānau, friends, or healthcare providers.

If you agree for your baby to take part in this study, you will be asked to sign the Consent Form on the last page of this document. You will be given a copy of both the Participant Information Sheet and the Consent Form to keep. This document is 4 pages long, including the Consent Form. Please make sure you have read and understood all the pages.

This study has ethical approval from the Central Health and Disability Ethics Committee (19/CEN/189).

**WHAT IS THE PURPOSE OF THE STUDY?**

Low blood sugar levels are a common problem in newborn babies. Babies need a constant supply of blood sugar to provide energy for the brain. In some babies, if blood sugar falls very low or is low for too long, brain injury can occur. This can cause problems with later concentration, coordination and learning. Therefore, babies at risk of low blood sugar levels have blood tests to check their sugar levels and are treated if the levels are low.

If initial measures such as extra feeding and dextrose gel rubbed into the mouth do not correct the low blood sugar, babies are usually admitted to the neonatal unit and given intravenous sugar ("drip"). However, being on a drip often delays breastfeeding and giving too much sugar by a drip can make problems worse. Some babies who need a drip are admitted for many days or occasionally for weeks.

We are looking for better ways to treat low blood sugar in babies. The aim of the NeoGluCO study is to investigate if a medicine called diazoxide given by mouth helps to keep the babies’ blood sugar levels stable, get them off drips faster, establish full feeding and spend less time away from their mothers.

Diazoxide is a medicine that helps control the release of insulin (the hormone that lowers blood sugar). Babies with low blood sugar usually make too much insulin. Diazoxide can correct this problem. Diazoxide is often used in babies if the low blood sugar level is not corrected by sugar from a drip. In this study we want to find out if it is better to give diazoxide earlier rather than later. We expect that most babies will only need the medicine for several days. It can be weaned off while establishing feeding.

**WHAT WILL MY PARTICIPATION IN THE STUDY INVOLVE?**

Babies can enter the NeoGluCO study if they are born at 35 weeks’ gestation or more and are admitted to the neonatal unit in the first week after birth with repeated or severe low blood sugar. If you agree to your baby taking part, he/she will be assigned to either diazoxide treatment or a placebo (solution with no diazoxide), given twice a day by mouth (or feeding tube if your baby has one). Babies enrolled in the study will otherwise receive the same treatment as other babies admitted with low blood sugar.

Once your baby’s blood sugar is stable and any sugar by drip has been stopped, the study medicine will be...
gradually reduced. The study medicine can be continued while your baby is establishing feeding. We expect that diazoxide will help babies reach full feeding without the drip more quickly. The study medicine will be stopped before your baby is discharged.

Babies in NeoGluCO will have these study tests as extra to routine care:

**Continuous glucose monitoring.** A very fine sensor will be placed under the skin on the thigh to monitor sugar levels. If the monitor shows that the blood sugar is decreasing or increasing too quickly, the team will be alerted to perform a blood sugar test. The sensors are very well tolerated by babies and will assist in close monitoring of sugar levels.

**Blood sample.** A small amount of blood will be taken 36 hours after starting the study medication (about half a teaspoon). Samples will be stored at the Liggins Institute, University of Auckland for later measurement of insulin, creatinine (a measure of kidney function) and the study medicine.

**Heart scan.** Babies at Middeomore Hospital will have an ultrasound scan of the heart at around 72 hours after entering the study.

**Blood sugar testing.** Blood sugar will be monitored at least every 12 hours while using the study medicine. Babies normally need regular blood sugar testing until they are taking full feeds and have had stable sugars for at least 24 hours.

We will collect general health information about your baby’s pregnancy, birth and admission from health records. With your permission, we will send a letter to your family doctor (GP) advising about your baby’s participation in the study. Research staff may contact you again when your baby is older to assess his/her development.

We would also like to ask for your permission to use routinely collected data on your child’s future health and education until they turn 16 years old. If you agree, we will get this information through either the Statistics New Zealand national Integrated Data Infrastructure (IDI) or from relevant government departments, e.g., Ministry of Health or Ministry of Education. The information would include hospital and GP visits, medications, growth and development at the Before School Check, and school progress. You do not have to agree to allowing us to use these data to participate in the study.

Data within the IDI are strictly controlled by Statistics New Zealand to protect privacy and prevent individuals being identified. Data is only accessible within secure ‘datalabs’ established by Statistics New Zealand and researchers can only retrieve a summary of results, not individual records of participants. If data are obtained directly from government departments, then the information is sent securely to the study investigators.

**WHAT ARE THE POSSIBLE BENEFITS AND RISKS OF THIS STUDY?**

**BENEFITS:** We cannot promise that your baby will get any benefits from this study. However, possible benefits include more stable blood sugar levels and less time on a drip if the diazoxide helps. The continuous glucose monitor will detect if the blood sugar goes too low or high. The results of this study will be used to improve the care of babies with low blood sugar in the future.

**RISKS:** Diazoxide has been used for many years to treat infants with high insulin release due to genetic problems with a good safety profile. It has also been used safely in children with diabetes and adults after obesity surgery. In a recent trial of diazoxide in 30 newborn babies, no side effects were seen. However, all medications can have side effects. Diazoxide has occasionally been associated with babies retaining too much fluid, which can cause breathing problems, but we expect this to be rare with short-term low dose treatment and to resolve quickly with stopping the medicine. The dose used in this study is the lowest dose recommended for children.

**WHO PAYS FOR THE STUDY?**

This research is being conducted by a collaborative group of clinical researchers based at University of Auckland, Counties Manukau Health and Auckland City Hospital. Funding has been provided from the University of Auckland. There are no costs associated with participation in this study.
WHAT IF SOMETHING GOES WRONG?

If your baby were injured in this study, which is unlikely, you would be eligible to apply for compensation from ACC just as you would be if you were injured in an accident at work or at home. This does not mean that your claim will automatically be accepted. You will have to lodge a claim with ACC, which may take some time to assess. If your claim is accepted, you will receive funding to assist in your baby’s recovery.

If you have private health or life insurance, you may wish to check with your insurer that if your baby takes part in this study, his or her cover won’t be affected.

WHAT ARE MY RIGHTS?

Participation in this study is voluntary. If you join the study but change your mind you can withdraw your baby at any time and your baby’s usual medical care will not be affected. With your consent, data collected prior to your withdrawal will be used in study analysis.

You and your baby’s privacy will be protected. Study data will be de-identified and any identifiable data, such as name and address, will be held securely, accessible only to the immediate research team. Project reports will not identify any individual participants. You may request to view your baby’s study data at any time and can be provided with a copy of his/her data.

WHAT HAPPENS AFTER THE STUDY?

When the study is completed, if you agree, we will write to you outlining the main findings of the study. This is not likely before 2022. If your baby had blood collected during the study, any leftover blood will be destroyed at the end of the study. If you would prefer, we can arrange a ceremony to dispose of the samples with a karakia (blessing). Electronic records will be permanently archived at the Liggins Institute, University of Auckland. Hard copy records will be kept securely for 25 years and will be accessible only to the study investigators. We may contact you in the future about enrolling your child in later follow-up studies to investigate the longer-term effects of the study treatment into childhood. De-identified study data may be made available to other researchers for approved future research.

WHO DO I CONTACT FOR MORE INFORMATION OR IF I HAVE CONCERNS?

If you have any questions, concerns or complaints about the study at any stage, you can contact:

Principal Investigator: Dr Chris McKinlay
Phone: +64 274725099
Email: c.mckinlay@auckland.ac.nz

Co-Investigator: Dr Jane Alsweiler
Phone: +64 21526363
Email: j.alsweiler@auckland.ac.nz

If you want to talk to someone who isn’t involved with the study, you can contact an independent health and disability advocate on:

Phone: 0800 555 050
Fax: 0800 2 SUPPORT (0800 2787 7678)
Email: advocacy@hdc.org.nz

You can also contact the health and disability ethics committee (HDEC) that approved this study on:

Phone: 0800 4 ETHICS
Email: hdecs@moh.govt.nz

If there is a specific Māori issue/concern please contact: Leigh Henderson, Chair CMDHB Māori Research Review Committee, +64 9 2629562, x3162
Consent Form — Neonatal Glucose Care Optimisation (NeoGluCO) Study

DECLARATION BY PARENT / GUARDIAN

I have read and I understand the Participant Information Sheet.
I have had time to consider whether to allow my child to take part.
I have had the opportunity to discuss this study and I am satisfied with the answers I have been given.
I have had the opportunity to use whānau/ family support or a friend to help me ask questions and understand the study.
I understand that the participation of my child in this study is my choice and that he/she may withdraw from the study at any time and this will not affect his/her continuing health care.
I consent to the research staff accessing my baby’s medical records and those relevant to this pregnancy.
I understand that any information collected about my child through the study will be kept confidential and that no material that could identify me or my child will be used in any study reports.
I know who to contact if I have any questions about the study in general.
I understand the compensation provisions in case of injury during the study.
I understand that I can request that my child’s blood samples be destroyed but I will not be able to have them returned.
I would like my baby’s blood samples to be disposed of with a Karakia (blessing).  Yes □ No □
I wish to receive a summary of the results of this research when they are available.  Yes □ No □
If I decide to withdraw my child from the study, I agree that the information collected up to the point when I withdraw may continue to be processed.  Yes □ No □
I consent to investigators accessing my child’s health and school records up to 16 years of age for study purposes only, from government departments or Statistics NZ.  Yes □ No □
You may contact me in the future to ask about my child participating in further aspects of the study.  Yes □ No □
You may notify my GP of my child’s participation in the study.  Yes □ No □

Declaration by parent / guardian: I hereby consent to my child taking take part in this study.

Child’s name:  Study ID:

Parent / guardian’s name:

Signature:  Date:

Declaration by member of research team: I have given a verbal explanation of the research project to the parent / guardian and have answered his/her questions. I believe that he/she understands the study and has given informed consent for this child to participate.

Researcher’s name:

Signature:  Date: