Participant Information Sheet

Information for whānau of a pēpi/baby with a normal newborn screening test for congenital hypothyroidism (controls).

You are invited to take part in the '**Hypothyroidism in Preterm Babies Study'*.***

Whether or not you participate (take part) is your choice. If you don't want to take part, you don't have to give a reason, and it won't affect the care you or your baby receives. Also, if you decide to take part now, but change your mind later, you can pull out of the study at any time. This also will not affect the care you or your baby receives.

This Participant Information Sheet will help you decide if you would like to be a part of the study. It explains why we are doing the study, what it would involve, what the benefits and risks to you 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.

If you agree 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 8 pages long, including the Consent Form. Please make sure you have read and understood all the pages.

WHAT IS THE PURPOSE OF THE STUDY?

This study aims to find out if babies born prematurely (before their due date) with congenital hypothyroidism have low iodine levels, so that we can provide better advice to pregnant mothers/parents and better nutrition to premature babies.

Virtually all newborn babies in New Zealand have a screening test (known as the Guthrie card) performed on the second day of life that tests for a range of important inborn illnesses that can cause death or disability. One of these illnesses is congenital hypothyroidism, a condition where the baby's thyroid gland cannot make enough thyroid hormone.

Congenital hypothyroidism (being born with an underactive thyroid) is the most common disorder detected by newborn screening and worldwide is the most common cause of preventable brain damage. Congenital hypothyroidism has become increasingly common in babies born before their delivery date (preterm), and it is even more common in Māori and Pasifika babies. It is important to understand and try to prevent this, as congenital hypothyroidism often leads to years of treatment and blood tests, which is a burden and a worry for families. Insufficient treatment can also affect the baby's development. We don't know why congenital hypothyroidism is increasing in premature babies, but we suspect it relates to low iodine in mothers and babies.

Iodine is a mineral necessary for the body to produce thyroid hormone, and New Zealand as a country has poor iodine levels in its soil, which leads to low levels in our food. Women are recommended to take iodine in pregnancy and while chest- or breast-feeding, but many do not take it, or do not take it regularly. Currently, low levels of iodine are provided in the specialised feeds given to newborn babies who are born prematurely.

The main aim of this study is to compare how much iodine is in the urine of preterm babies who have congenital hypothyroidism with preterm babies who don't have congenital hypothyroidism.

You have been asked if you would like to be a part of this study as a 'control' as your baby has a normal screening test or is the twin sibling of a baby in our study. We want to compare the iodine levels between babies with an underactive thyroid with those who have a normal thyroid.

Ethical approval has been obtained from the New Zealand Health and Disability Ethics Committee (HDEC) 2024 FULL 20016.

WHAT WILL PARTICIPATION IN THE STUDY INVOLVE?

Participation in this study does not affect your care during your baby's stay in hospital. You will still have a medical team who will be responsible for the health of your baby while they are in hospital.

We will seek your permission to access your baby's Newborn Metabolic Screening blood results from heel prick samples they have already had taken and do not require any additional heel pricks or blood tests from your baby on top of their usual care.

Your participation would involve a questionnaire, measurement of blood, urine and breast milk samples from you (the mother/childbearing parent) and a urine sample from your baby at the beginning of the study. If you have twin babies in the study, we would other collect your samples and information once. We will also record the nutritional information for your baby throughout the study and repeat urine testing from your baby at the end of the study (36 weeks corrected gestational age).

Babies who are found to have congenital hypothyroidism during the study will be diagnosed and treated as they usually would, with thyroid replacement therapy by their medical team. Your baby's urinary iodine results will be passed on to their medical team. Your thyroid function blood results, if abnormal, will be passed on to you and, with your permission, to your LMC or GP. You can request your blood and urine test results at any time.

The following tests or information will be collected from you (mother/childbearing parent):

- Questionnaire (15 minutes)

  At the start of the study, you will be asked to complete a questionnaire that provides us with background information. A research nurse will ask questions about your medical history, in particular about thyroid conditions and use of iodine supplements during pregnancy. These answers will be recorded digitally. You can request a copy of the questionnaire at any time.

- Blood tests

At the start of the study we will collect a blood sample from you. The blood sample will be taken from a vein in your arm. The blood volume taken is small (less than one teaspoon).

- Urine sample

  At the start of the study we will ask for a urine sample from you. This sample will ideally be a morning sample and we need up to 20 mL. We would prefer if this is your first urine of the day, before you have eaten or drunk anything other than water.

- Breast milk sample

  At the start of the study we will ask for a breast milk sample from you. This sample will be ideally a morning sample from your first milk expression of the day (before breakfast) and we need approx. 5mL (less than one teaspoon). You may collect it however you prefer, whether by hand-expressing from your breast/chest, or using a manual or electric breast pump.

The following tests or information will be collected from your baby:

- Results from previous blood tests/heel pricks

  We will seek permission from you to look at the results of standard heel prick samples as part of Newborn Metabolic Screening (Guthrie card). These are tests your baby has already had or will have as part of the usual screening tests.

  If your baby has an abnormal result on screening, your clinical care team will perform a further blood test to confirm results and we will seek your permission to access these results. Your baby will not need to have any extra blood tests or heelpricks as part of the study.

- Urine sample

  At the start of the study we will collect a urine sample from the baby. This is caught with a urine bag. Another urine sample will be collected at the end of the study (36 weeks). We will aim to collect your baby's urine sample in the morning, before a morning feed.

- Nutritional data collection
  Throughout the study, we will keep track of your baby's nutritional information, including any intravenous (through their veins) nutrition they receive, breast or formula milk and any supplements or fortifiers.

If you are of Māori descent, you are encouraged to consult with your whānau, hapu or iwi regarding participation in this project. You may hold beliefs about a sacred and shared value of all or any tissue samples removed. The cultural issues associated with sending or storing tissue should be discussed with family/whānau as appropriate. There are a range of views held by Māori around these issues; some iwi disagree with storage of samples, citing whakapapa, and advise their people to consult prior to participation in research where this occurs. However, it is acknowledged that individuals have the right to choose. In addition, if at completion of the study you wish to have the blood/urine/breast milk samples returned to you, or if you withdraw consent for the use of your samples in this study, this will be arranged.

Optional Iodine Variability Sub-study

You may be invited to participate in an optional (your choice, added extra) sub-study which would involve extra urine and breast milk samples. We would ask for an additional daily sample of urine and breast milk from you and an additional daily sample of urine from your baby for 6 extra days after you first begin the study. We would like these samples to be at the same time each day, first thing in the morning before eating or drinking anything other than water. This will be to help us learn about how iodine levels vary from day to day. This is optional and if you choose not to participate, your care, and involvement in the main study will not be affected

WHAT HAPPENS TO MY SAMPLES?

Samples from you

Blood samples from you at the start of the study will be tested to measure the levels of thyroid hormones in your body.

Urine samples from you at the start of the study will be tested for their iodine concentration to give us information on your iodine stores within your body.

Breast milk samples from you at the start of the study will also be tested for their iodine concentration to give us information on your iodine stores within your body, and how much iodine your baby can receive through breast milk.

Samples from your baby

Urine samples from your baby at the start and end of the study will be tested for their iodine concentration to give us information on the iodine stores within your baby's body.

Return of samples and Karakia

The blood and urine samples will be tested quickly after they are taken and are unable to be returned after this, unless you tell us in advance. If you wish them back after testing, please let us know in your consent form. We are unable to perform karakia at the time of sample disposal.

You can request the return of the breast milk samples before and after testing. Please be aware that due to the way they are stored, they are not suitable for your baby (or anyone else) to eat as they will not be stored as per food storage guidelines. Please let us know in your consent form if you would like them back.

If you change your mind and wish for your samples to be returned, please let us know as soon as possible by contacting the research nurse or study members listed below (Dr Ashleigh Brown or Dr Ben Albert). We cannot guarantee return of samples if you change your mind so please think carefully before giving your sample.

WHAT ARE THE POSSIBLE BENEFITS AND RISKS OF THIS STUDY?

Benefits

The benefits of this study are to help us understand how thyroid function and low iodine levels relate to each other in premature babies and their mothers/childbearing parents. Being part of this project may help us to improve understanding about iodine needs in premature babies. You will also learn about your baby's health.

Risks

There are minimal risks to you and your baby. No treatments will be initiated by the study team.

This study includes blood tests for mothers/childbearing parents which could cause discomfort and worry in some people. This is minimised as it is done by a highly skilled phlebotomist at the hospital. No extra blood test/heel prick is taken from your baby as part of the study.

The urine tests are collected with a urine bag that is a painless and non-invasive way to collect urine from a baby. It is possible that the bag could irritate the skin but is unlikely.

Confidentiality

All information and data collected in this study will be stored in strict confidence, and no material that can personally identify you will be used in any reports on this study. All information will be stored within a password-protected database within the University of Auckland that is only accessed by the study team. Any information that could be traced back to you will be removed from the database before any information is analysed.

It is possible that during the course of the study, a health problem could be discovered that you would benefit from your health professionals such as your midwife or General Practitioner (family doctor) knowing about. We would communicate this to them if you were willing for us to do so.

What will my participant cost?

Your participation will **not** lead to any costs to you. We would like to offer you a small koha or compensation after you have completed the questionnaire and we have gathered the first sets of samples to show our appreciation for your participation and time.

What are my rights? What if I change my mind?

Involvement in this study is entirely voluntary (your choice). If you choose not to take part, this will not affect any future care or treatment. If you agree to take part, you will be free to withdraw from the study at any time. Also, if we feel that your participation in this study is not in your best interest, we will withdraw you from the study. If you withdraw prior to the questionnaire and first samples, you will not receive the koha/compensation.

What happens after the study?

All information will be stored in a locked filing cabinet at our clinical research unit, and in computer files that are locked with a password. You and your baby's data will be stored for 26 years, but it will not be sent away to people outside of the study.

THE UNIVERSITY OF AUCKLAND
Te Whare Wānanga o Tāmaki Makaurau
NEW ZEALAND

LIGGINS INSTITUTE

Blood and urine samples will be disposed of soon after analysis by the hospital laboratory. Breast milk samples may be stored for up to 10 years, then they will be disposed of by incineration as per the guidelines for the 'Destruction of Human Tissue Samples' at the University of Auckland. If, at the completion of the study, you advise us that you wish to have your breast milk samples returned, this will be arranged.

We will share the results of the study with you at the end of the study if you would like us to. This can include your individual results (and the results for your baby). It is important to understand that many of the results will be important for the scientific research but will not mean much for you or your baby. We can also provide you the overall results of the study. We will always be accessible if you have questions about any of our findings or individual test results.

All information from this study that is published will be made anonymous (unable to be traced back to you). This could include sharing anonymous information in an online repository (place where other researchers can view it, including researchers outside of New Zealand). No result will be able to be traced back to you or your baby.

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:

Dr Ashleigh Brown
Paediatric Endocrinology Fellow & PhD Candidate, Liggins Institute, University of Auckland
Phone: 09 923 4476
Email: Abro246@aucklanduni.ac.nz

Dr Ben Albert
Senior Research Fellow and Paediatric Endocrinologist, Liggins Institute, University of Auckland Phone: 09 923 4476
Email: b.albert@auckland.ac.nz

If you want to talk to someone who is not 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

These health and disability advocates have expertise in Māori and Pacific Health, as well as other major cultures.

You can also contact the Health and Disability Ethics Committee (HDEC) that approved this study:

Phone:0800 400 569 Email: hdecs@health.govt.nz

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. If you have any questions or complaints about the study you may contact the Auckland and Waitematā District Health Boards Māori Research Committee or Maori Research Advisor by phoning 09 4868920 ext 3204.