



The CHYLD Study Children with Hypoglycaemia and their Later Development

Four and a Half year Follow-up

Parent/Guardian Information

Why my child?

We are writing to you because when your baby was born s/he took part in a study looking at low blood sugar levels in newborn babies (the BABIES or SUGAR BABIES studies). Those studies included measuring your child's sugar levels using a small sensor in his/her leg. You and your child may also have taken part in the CHYLD study looking at growth and development at two years of age. We would now like to invite you and your child to take part in a new study to look at the growth and development of children who were part of those studies and are now four and a half years of age.

Your participation is entirely voluntary (your choice). You do not have to take part in this study, and if you choose not to take part this will not affect any future care or treatment for either you or your child. If you do agree to take part in the study, you are free to withdraw from the study at any time, without having to give a reason, and this will in no way affect your or your child's future health care.

Why is this study important?

Low blood sugar levels are a common problem in newborn babies. Some children who had low blood sugar levels as babies may show later effects of this as they grow up. However, we do not know which babies might be affected. We need to know more about how children develop after low and not so low blood sugar levels. This would help us in the future to know which babies need blood tests and other treatments, and which do not.

What is the CHYLD study?

The aim of the CHYLD study is to assess children who had their sugar levels measured soon after birth as part of the BABIES or SUGAR BABIES studies. If your child takes part, we will arrange a time that suits you for us to assess his/her growth and development. This can be at our Research House on Kahikatea Drive, Hamilton, or at a location closer to your home if you do not live in Hamilton. We will give you a petrol voucher to cover your travel costs for this.

Your child will see a psychologist, a doctor and an eye specialist. The assessments are often used with children of this age and include a number of games. The visit will take 2.5 – 3.5 hours, with breaks for food and rest. **This assessment does not include blood tests.**

To make sure our assessments maintain a high standard some of them will be videotaped. We will only do this for your child if you agree to this. This recording is only for the use of the study team.

What are the possible benefits and risks to my child?

This study is not likely to be of immediate benefit to your child, and does NOT replace the B4 School Check offered by the Ministry of Health. Instead the information we gather is likely to be of benefit to future babies born at risk of low blood sugar levels. However, because we will be assessing your child's growth and development, you will be given this information about your child, and many parents find this reassuring. If we discover any areas of concern we will discuss this with you and help you decide if any further help is needed.

CHYLD



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

Children with Hypoglycaemia and their Later Development

We do not think there are any risks to your child if they take part in this study.

Results

Your child's assessment results will be discussed with you and a summary of the results will be sent to your GP if you agree. If you have any concerns about your child's health and would like the results sent to another health professional we can do that for you. The results from the completed study will be published in a scientific journal. The information will be presented in such a way that neither you nor your child can be identified in any way. A summary of the results will be sent to you if you show on the consent form that you would like to receive this. This is not likely to be before 2015.

Statement of Approval

This study has ethical approval from the Northern Y Regional Ethics Committee.

Compensation

In the unlikely event of a physical injury as a result of your participation in this study, you may be covered by ACC under the Injury Prevention, Rehabilitation, and Compensation Act 2001. ACC cover is not automatic, and your case will need to be assessed by ACC according to the provisions of the Injury Prevention, Rehabilitation, and Compensation Act 2001. If your claim is accepted by ACC, you still might not get any compensation. This depends on a number of factors, such as whether you are an earner or non-earner. ACC usually provides only partial reimbursement of costs and expenses, and there may be no lump sum compensation payable. There is no cover for mental injury unless it is a result of physical injury. If you have ACC cover, generally this will affect your right to sue the investigators.

If you have any questions about ACC, contact your nearest ACC office or the investigator.

Questions?

If you need an interpreter one will be provided.

If there is a specific Maori issue/concern please contact Te Puna Oranga (Maori Health Services at Waikato District Health Board) Telephone 07 839 7644.

If you have any queries or concerns regarding your rights as a participant in this study, you may wish to contact an independent health and disability advocate: Free phone: 0800 555 050 Free fax: 0800 2 SUPPORT (0800 2787 7678) Email: advocacy@hdc.org.nz

If you wish to know anything further about this study, at any stage, please ask your baby's nurse or doctor or contact the lead researcher: Professor Jane Harding.

Principal Investigator: Professor Jane Harding, Professor of Neonatology, Liggins Institute,
University of Auckland,
Ph 09 373 7599 ext 86439
Study free phone 0800 249 537 or mobile 021 980 913