

Statement of approval

This study has ethical approval from the New Zealand Health and Disability Ethics Committee. Ref 13/NTA/8

Compensation

If you were injured in this study, which is unlikely, you would be eligible for compensation from ACC just as you would be if you were injured in an accident at work or at home. 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 recovery. If you have private health or life insurance, you may wish to check with your insurer that taking part in this study won't affect your cover.

If you wish to know anything further about this study (either now or at any later date) please feel free to ask your midwife, your baby's doctor or nurse, one of the researchers at your hospital or one of the trial investigators; Dr Jane Alsweiler or Professor Jane Harding.

Speak with your Lead Maternity Carer

Or

Insert sticker for local site research nurse

After hours

Freephone: 0800 00 hPOD

Insert sticker for local site investigator

Principal Investigator

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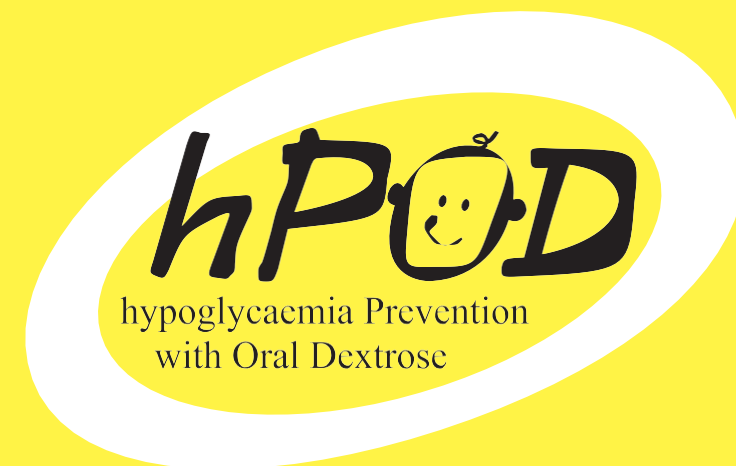
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Freephone hPOD trial information

0800 00 hPOD

or email hPOD@auckland.ac.nz



hPOD Study Parent Information

Why is this study important?

Low blood sugar levels are a common problem in newborn babies. In some babies if the blood sugar levels are very low this can sometimes cause brain damage. This is why all babies at risk of low blood sugar levels have blood tests to check their sugar levels and are treated if the levels are low. This often means the baby needs to go to the Newborn Intensive Care Unit/ Special Care Baby Unit.

The aim of this study is to find out if giving dextrose (sugar) gel to babies who are at risk of low blood sugar levels helps keep their blood sugar levels normal, avoids the need to go to the Newborn Intensive Care Unit/ Special Care Baby Unit and reduces formula feeding, therefore supporting breastfeeding.

Why my baby?

Your baby will be at risk of having low blood sugar levels, either because you have diabetes; the baby may be born preterm, or the baby may be smaller or larger than normal. Therefore you are invited to consider your baby taking part in a research study. This study will look at preventing low blood sugar levels in babies.

Taking part in this study is voluntary (your choice) and you do not have to enrol your baby in this study. If you choose not to take part it will not affect any future care or treatment of your baby. If you do agree to take part you are free to withdraw your baby from the study at any time. You will not need to give a reason. This will in no way affect your baby's health care.

What does the study involve?

Babies who are enrolled in the study will receive

exactly the same care as all the other babies born at risk of low blood sugar levels. This includes regular blood tests to check blood sugar levels.

If you agree to enrol your baby in this study, you will be encouraged to feed your baby, and your baby will also receive one of two gel solutions. One gel is a 40% sugar gel and the other is placebo gel with no sugar. The gel will be rubbed into the inside of the baby's cheek 1 hour after birth. The study does not involve any extra blood tests.

If your baby has a low blood sugar level he or she will be treated in the usual way.

A member of the research team will contact you by phone when your baby is 3 days old and when 6 weeks old to ask about your baby's feeding.

We would also like to get the details of both mother's and baby's care from the hospital records.

We may wish to contact you when your baby is around 2 years old. This would be to find out whether the gel may have helped your baby's later health and development. We would tell you about any extra study at that time and ask your consent for your baby to take part.

What are the benefits and risks for my baby?

Your baby may benefit from this study if the gel helps keep your baby's blood sugar levels normal and saves your baby needing further treatment in the Newborn Intensive Care Unit/Special Care Baby Unit.

We do not expect that this study will cause any harm to your baby. The sugar gel is used to treat babies who already have low blood sugars, without any problems.

Results

The results from the study will be published in a

scientific journal. No material that could personally identify you or your baby will be used in any reports. A summary of the results will be sent to you when the study is finished, if you mark on the consent form that you would like to receive this. This is not likely to be before 2017.

Questions?

- If you need an interpreter one will be provided.
- You may wish to discuss participation in this research trial with your own whānau, hapu or kaumātua support networks in the first instance. Alternatively you may contact:

- If you have any questions or complaints about the study you may contact the District Health Board's Māori Research Committee or Māori Research Advisor:

- If you have any queries or concerns about your rights as the parent of a baby in this study you may wish to contact a Health and Disability Advocate, on free phone: 0800 555 050.