

# Implementation of a guideline in babies on postnatal wards

<b>Submission date</b> 11/05/2015	<b>Recruitment status</b> No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
<b>Registration date</b> 20/05/2015	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 29/09/2023	<b>Condition category</b> Pregnancy and Childbirth	<input type="checkbox"/> Individual participant data

## Plain English summary of protocol

### Background and study aims

Neonatal hypoglycaemia is the term used to describe low blood sugar levels in babies in the first few days after birth. Newborn babies with low blood sugar are usually treated with extra feedings (breast milk or formula); in some cases the baby will need to be fed a sugar solution using a drip. Treatment is carried out until the baby's sugar levels become stable, which can take from hours to days, or even longer. In New Zealand, a new national guideline on treating neonatal hypoglycaemia using dextrose (sugar) gel has been developed. However, it is unclear who the best people are on the ward to put the new guideline in place: midwives or doctors. This is because newborns on postnatal wards are routinely cared for by midwives, while doctors are there to provide medical treatment for sick babies. The aim of this study is to see whether it is doctors or midwives that are best placed to implement a new guideline for changing clinical practice for babies on postnatal wards.

### Who can participate?

New Zealand maternity hospitals with more than 50 births per year.

### What does the study involve?

Participating hospitals are randomly allocated into one of two groups. Hospitals in group 1 have a medical leader appointed to implement a guideline on treating neonatal hypoglycaemia with dextrose gel. Hospitals in group 2 have a midwifery leader appointed to implement a guideline on treating neonatal hypoglycaemia with dextrose gel. The change in the number of eligible hypoglycaemic babies treated with dextrose gel is compared from before the implementation of the guideline and then again 3 months afterwards.

### What are the possible benefits and risks of participating?

Participation in the trial will help determine the most effective local leader to implement a guideline on the postnatal wards. The results will also potentially aid in the implementation of an effective neonatal treatment. There are no specific risks associated with participation in this study.

### Where is the study run from?

University of Auckland (NZ)

When is the study starting and how long is it expected to run for?  
May 2015 to March 2018

Who is funding the study?  
Gravida: National Centre for Growth and Development (NZ)

Who is the main contact?  
Dr J Alsweiler

## Contact information

**Type(s)**  
Scientific

**Contact name**  
Dr Jane Alsweiler

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## Additional identifiers

**Protocol serial number**  
U111-1167-9170

## Study information

**Scientific Title**  
Local clinical leaders to implement a national guideline in babies on postnatal wards: a cluster-randomised, blinded, controlled trial

**Study objectives**  
Midwives are the most effective local leaders for implementing a guideline for use of oral dextrose gel to treat neonatal hypoglycaemia.

**Ethics approval required**  
Old ethics approval format

**Ethics approval(s)**  
New Zealand Northern A Health and Disabilities Ethics Committee, 19/03/2015, ref: 15/NTA/31.

**Study design**

Multi-centre cluster blinded randomized controlled trial

## Primary study design

Interventional

## Study type(s)

Other

## Health condition(s) or problem(s) studied

Neonatal hypoglycaemia

## Interventions

Current interventions as of 01/02/2022:

Participating hospitals will be randomised:

1. Medical leader to implement a guideline on oral dextrose gel to treat neonatal hypoglycaemia
2. Midwifery leader to implement a guideline on oral dextrose gel to treat neonatal hypoglycaemia

Previous interventions:

Participating hospitals will be randomised:

1. Intervention group will have a medical or midwifery leader to implement a guideline on oral dextrose gel to treat neonatal hypoglycaemia
2. Control group will deliver standard care

## Intervention Type

Behavioural

## Primary outcome(s)

The change in the proportion of eligible hypoglycaemic babies treated with dextrose gel before implementation of the dextrose gel guideline to three months after implementation.

## Key secondary outcome(s)

Current secondary outcome measures as of 01/02/2022:

1. Proportion of eligible babies admitted to NICU for at least 4 hours
2. Proportion of eligible babies given formula as a treatment for hypoglycaemia during hospital admission
3. Amount of dextrose gel used in the hospital
4. Prolonged uptake of dextrose gel (change in proportion of eligible babies treated with dextrose gel before implementation of the guideline to 6 months after implementation)
5. Sustained use of dextrose gel (change in proportion of eligible babies treated with dextrose gel from 3 months after implementation to 6 months after implementation)
6. Successful treatment with oral dextrose gel on the blood test taken immediately following dextrose gel treatment
7. Adherence to the 'oral dextrose gel to treat neonatal hypoglycaemia guideline'
8. Breastfeeding at discharge

Previous secondary outcome measures:

1. Proportion of eligible babies admitted to NICU for at least 4 hours
2. Proportion of eligible babies given formula as a treatment for hypoglycaemia during hospital admission
3. Amount of dextrose gel used in the hospital

4. Initial uptake of dextrose gel (change in proportion of eligible babies treated with dextrose gel before implementation of the guideline to 1 month after implementation)
5. Sustained use of dextrose gel (change in proportion of eligible babies treated with dextrose gel from 1 month after implementation to 3 months after implementation)
6. Successful treatment with oral dextrose gel on the blood test taken immediately following dextrose gel treatment
7. Adherence to the 'oral dextrose gel to treat neonatal hypoglycaemia guideline'
8. Breastfeeding at discharge

**Completion date**

31/03/2019

## Eligibility

**Key inclusion criteria**

Doctors and midwives attached to New Zealand maternity hospitals with >50 births/year where babies are at risk of neonatal hypoglycaemia (infant of a diabetic, late preterm, small or large for gestational age) are delivered, including hospitals where oral dextrose gel is currently in use.

**Participant type(s)**

Health professional

**Healthy volunteers allowed**

No

**Age group**

Mixed

**Sex**

All

**Total final enrolment**

463

**Key exclusion criteria**

Hospitals in NZ without a doctor (paediatrician or general practitioner) available to provide medical treatment, or no midwifery care for newborn babies.

**Date of first enrolment**

01/06/2015

**Date of final enrolment**

13/06/2018

## Locations

**Countries of recruitment**

New Zealand

**Study participating centre**  
University of Auckland  
Auckland  
New Zealand  
1010

## Sponsor information

### Organisation

University of Auckland

### ROR

<https://ror.org/03b94tp07>

## Funder(s)

### Funder type

Research organisation

### Funder Name

Gravida: National Centre for Growth and Development (NZ)

## Results and Publications

### Individual participant data (IPD) sharing plan

Not provided at time of registration

### IPD sharing plan summary

Available on request

### Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Results article</a>		28/09/2023	29/09/2023	Yes	No
<a href="#">Protocol article</a>	protocol	22/11/2017	17/12/2020	Yes	No