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Implementation of a guideline in babies on postnatal wards

Submission date
11/05/2015

Recruitment status
No longer recruiting

Registration date
20/05/2015

Overall study status
Completed

Last Edited
29/09/2023

Condition category
Pregnancy and Childbirth

[X] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[X] Results
[_] 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

ORCID ID
http://orcid.org/0000-0002-0874-6654

Contact details
University of Auckland
Private Bag 92019
Auckland
New Zealand
1142

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Other

Participant information sheet
Not available in web format, please use contact details to request a participant information sheet.

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 measure
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.

Secondary outcome measures
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

Overall study start date
01/05/2015

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

Age group
Mixed

Sex
Both

Target number of participants
34 hospitals and approximately 1250 babies born during the study period

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

Sponsor details
Private Bag 92019
Auckland
New Zealand
1142

Sponsor type
University/education

ROR
https://ror.org/03b94tp07

Funder(s)

Funder type

Research organisation

Funder Name
Gravida: National Centre for Growth and Development (NZ)

Results and Publications

Publication and dissemination plan
Planned publication the results of our study via a number of avenues including submitting an article to a peer-reviewed scientific journal, conference presentations and website publication.

Intention to publish date
31/03/2019

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?
Protocol article	protocol	22/11/2017	17/12/2020	Yes	No
Results article		28/09/2023	29/09/2023	Yes	No