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Support with or without formula trial for infants at risk of hypoglycaemia

Submission date 02/12/2022	**Recruitment status** No longer recruiting	[X] Prospectively registered [_] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [_] Record updated in last year
Registration date 20/01/2023	**Overall study status** Completed	
Last Edited 19/01/2024	**Condition category** Pregnancy and Childbirth	

Plain English summary of protocol

Background and study aims
Newborn babies may be at risk of developing low blood sugars (hypoglycaemia) if they are born a few weeks premature (32-36 weeks of pregnancy), low birthweight (less than 2.5kg), or if their mother has pregnancy complications such as poor fetal (baby) growth or diabetes. Many of these babies/pregnancies are detected during pregnancy but some may occur without warning. Most of these babies are able to tolerate milk, especially the mother's breastmilk, from the first day, but sometimes the amount of breastmilk produced in the first few days is of insufficient volume to meet the babies' needs. In this case, the baby is at risk of developing low blood sugar levels which may further worsen feeding or may harm the baby. For this reason, such babies are offered extra milk according to national guidelines which can be formula or donor human milk (DHM). Where formula milk is used as a supplement, there is a concern that this may adversely impact continued breastfeeding. We want to study whether the type of milk offered impacts the establishment of successful breastfeeding. The study aims to determine whether offering DHM increases the percentage of mothers who are still breastfeeding at hospital discharge compared to when formula milk is offered.

Who can participate?
Newborn infants are at risk of hypoglycaemia, and mothers who are likely to deliver an infant at risk but are still pregnant, for example, women attending antenatal clinics or who are on delivery suite (antenatal consent) may also be approached for consenting their child to participate

What does the study involve?
Babies born to mothers who consent will be randomised to receive either DHM or formula milk (standard treatment) if there is a medically indicated need for additional milk to prevent hypoglycaemia. The study is a randomised, non-blinded, controlled trial and enrolment is possible as long as the infant is less than 24 hours old.

What are the possible benefits and risks of participating?
There are no specific benefits to taking part, but if DHM increases the % of babies who have been discharged breastfeeding then those babies and women may benefit. There are no other interventions or tests for the baby, and there are no specific risks associated with the study.

Where is the study run from?
Royal Victoria Infirmary, Newcastle Hospitals NHS Trust (UK)

When is the study starting and how long is it expected to run for?
November 2022 to June 2024

Who is funding the study?
Newcastle Hospitals NHS Trust (UK)

Who is the main contact?
Prof Nicholas Embleton (Co-chief investigator), nicholas.embleton@ncl.ac.uk (UK)

Study website
https://www.neonatalresearch.net

Contact information

Type(s)
Principal Investigator

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number
302139

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
SWIFT 2.05, IRAS 302139

Study information

Scientific Title
Support WIth or without Formula Trial for infants at risk of hypoglycaemia (SWIFT): a pilot and feasibility trial

Acronym
SWIFT

Study objectives
The use of donated human milk (intervention) compared to formula milk (control) for otherwise stable infants at increased risk of hypoglycaemia on a postnatal ward and where there is a shortfall in "mother's own milk" (population), will improve breast-feeding rates (outcome) at hospital discharge.

Ethics approval required

Old ethics approval format

Ethics approval(s)
Approved 09/03/2023, East of England - Cambridge South Research Ethics Committee (Meeting held by video conference via Zoom; +44 (0)207 104 8084, (0)207 104 8109; cambridgesouth.rec@hra.nhs.uk), ref: 23/EE/0020

Study design
Randomized non-blinded controlled trial

Primary study design
Interventional

Secondary study design
Pilot, feasibility and embedded qualitative

Study setting(s)
Hospital

Study type(s)
Treatment

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

Health condition(s) or problem(s) studied
Newborn infants with risk factors for hypoglycaemia

Interventions
The SWIFT (Supplementation with or without formula trial) study is a pilot and feasibility trial, designed to compare the intended or actual use of donor human milk (DHM) where there is a medically indicated need to potentially provide extra milk (intervention) compared to formula milk (control) in mother's who wish to breastfeed.
Setting: Postnatal wards, Delivery suite, Neonatal Unit, Royal Victoria Infirmary
Population: Infants <24 hours of age and at risk of hypoglycaemia
Intervention: use of donated human milk
Control: use of formula milk
Timeframe: intervention available until 72 hours of age, or hospital discharge if earlier. If more than 72 hours of extra milk is required, then formula will be offered as this represents the current standard treatment.

Infants meeting the inclusion criteria (i.e. at-risk of hypoglycaemia) will be eligible for enrolment but will only receive the intervention/control milk where this is medically indicated. This is because it is difficult to predict which babies may need additional milk when they are firstborn. Furthermore, maternal behaviours towards continued breastfeeding may be affected by the knowledge of whether donor milk or formula milk might be used if medically needed. The most common time for extra milk to be required is in the first 48 hours, prior to the onset of full lactation. Most mothers experience the onset of lactation ("coming in") at around 2-3 days of age, and extra milk is usually not required after this period.

Enrolment and consent processes
Many mothers of infants likely to deliver at-risk infants (for example, preterm labour <37 weeks, maternal diabetes etc.) are already identified before delivery, and antenatal approach and consent are possible. This may take place in an antenatal clinic or antenatal ward, or in the delivery suite prior to delivery. For other infants, parents will be approached after delivery and within the first 3 hours of life since it is uncommon to receive supplemental milk before this. Because both formula and donor milk are already used within the NHS as standard care, we consider initial verbal assent to be an appropriate initial approach if a member of the research team is not available i.e. out of normal working hours. We have discussed this with parent PPI representatives who tell us this is acceptable in order that those families do not miss out on an opportunity to partake if they wish. Where parents assent, this will be followed by a member of the research team and confirmed by written consent within 24 hours. This may also remove the pressure from parents sometimes felt in studies with short time frames for recruitment and has been successfully utilised by the NIHR-funded FEED1 study, where intervention is needed within the first hours of life in a similar population. If parents initially assent to the use of donor milk, they will still be able to withdraw and decline continued participation in the study. The use of donor milk as part of this study does not pose any risk to the infant or the mother, and we feel that enabling this form of participation will enable participation from a more diverse population.

Randomisation processes
Infants will be randomised using sealedenvelope.com but we will provide 'hard' sealed envelopes for out-of-hours use. Where possible antenatal randomisation will occur, since most at-risk infants are identified before delivery (for example maternal diabetes, small for gestational age or low birthweight, maternal beta blockers). Where this has not been possible and a clinical member of the research team is not available out of hours, and where the parents are keen to take part, informed assent will be used prior to confirmation with signed consent within 24 hours. Parental assent will be documented in medical records. These parents will be randomised using a sequentially numbered 'hard' sealed envelope. These cases will be entered as "manually randomised" into the sealedenvelope.com system.

Intervention Type
Supplement

Primary outcome measure
Breastfeeding rate measured using electronic medical records at hospital discharge. This outcome is also met if a mother is actively expressing breastmilk which the infant receives wholly or in part via a bottle.

Secondary outcome measures
Breastfeeding rates and adverse outcomes measured daily using electronic medical records
1. Episodes of hypoglycaemia (Glucose <2.6mmol/L)
2. Adverse outcomes, for example, admission to the neonatal unit
3. Breastfeeding duration (any and exclusive) at discharge and by telephone call at 6 weeks, 3 months post-discharge
4. Use of nasogastric tube feeding or other supplemental feeding methods
5. Length of hospital stay
6. Stools day 0, day 3, 6 weeks corrected age (sent via post) by collection from nappy analysed for:
6.1. Microbiome (16s)
6.2. Calprotectin

Trial feasibility outcomes measured monthly using electronic medical and study records:
1. Recruitment rates/eligible infants per month
2. Numbers of infants:
2.1. Recruited before or after delivery
2.2. Recruited during normal working hours
2.3. Receiving non-MOM milk or hypoglycaemic before trial enrolment
3. Numbers of mothers:
3.1. Declining enrolment
3.2. Not returning completed questionnaires
3.3. Unable to contact by telephone post-discharge (lost to follow-up)

Overall study start date
01/11/2022

Completion date
01/09/2024

Eligibility

Key inclusion criteria
Newborn infants <24 hours of age who do not require admission for neonatal intensive care or intravenous therapy but who are at risk factors for hypoglycaemia:
1. Born at 32-36 weeks gestation
2. In-utero growth restriction (defined by unit guidelines)
3. Birthweight <2.5kg
4. Maternal use of B-blockers
5. Maternal diabetes
6. Other conditions where in the opinion of the medical and nursing team the infant requires additional milk to protect the infant's health

Participant type(s)
Patient

Age group
Neonate

Upper age limit
1 Days

Sex
Both

Target number of participants
160

Key exclusion criteria
1. Parents unwilling to accept donated human milk
2. Mother's not wishing to breastfeed
3. Infant requiring intravenous fluids at birth
4. Inability to randomise within 24 hours of birth

Date of first enrolment
04/05/2023

Date of final enrolment
31/05/2024

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Newcastle Hospitals NHS Foundation Trust
Richardson Road
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Sponsor information

Organisation
Newcastle upon Tyne Hospitals NHS Foundation Trust

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Sponsor type
Hospital/treatment centre

Website
http://www.newcastle-hospitals.org.uk/

ROR
https://ror.org/05p40t847

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Newcastle upon Tyne Hospitals NHS Foundation Trust

Alternative Name(s)
Newcastle upon Tyne Hospitals NHS Trust

Funding Body Type
Government organisation

Funding Body Subtype
Local government

Location
United Kingdom

Results and Publications

Publication and dissemination plan
1. Planned publication in a high-impact peer-reviewed journal
2. Presentions at conferences

Intention to publish date
01/04/2025

Individual participant data (IPD) sharing plan
The data-sharing plans for the current study are unknown and will be made available at a later date

IPD sharing plan summary
Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
HRA research summary			20/09/2023	No	No