ISRCTN81620277 https://doi.org/10.1186/ISRCTN81620277

Supplementary donor breast milk versus formula as a bridge to exclusive breast milk feeds at discharge in moderate and late preterm infants

Submission date
08/08/2025

Recruitment status
Recruiting

Registration date
03/11/2025

Overall study status
Ongoing

Last Edited
03/11/2025

Condition category
Pregnancy and Childbirth

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[X] Record updated in last year

Plain English summary of protocol

Background and study aims
Breast milk is the best food for babies, especially those born early (prematurely). It helps with brain development, reduces hospital stays, and supports mothers' wellbeing. However, premature babies are less likely to be breastfed than full-term babies. For very premature babies (born before 33 weeks), donor breast milk is often used when the mother's milk isn't available yet. It's better tolerated than formula and may reduce health problems.

This study wants to find out if using donor breast milk (instead of formula) to supplement the mother's milk in moderately premature babies (born between 33 and 35 weeks) helps babies feed better, go home sooner, and encourages mothers to continue breastfeeding.

Who can participate?
Families of babies born between 33 and 35 weeks at Southmead Hospital (Bristol) and Bath Hospital will be invited to take part, either before or shortly after birth.

What does the study involve?
-334 mothers will be randomly assigned to one of two groups: one group will receive donor breast milk as a supplement, and the other will receive formula, for the first 5 days of feeding.
-After 5 days, if extra milk is still needed, both groups will receive formula.
-The baby will always be given the mother's own milk first, if available.
-Doctors and mothers will decide together how and when to feed the baby.
-Information about the mother and baby will be collected during the hospital stay and up to 6 months after the baby's due date using questionnaires.
-Families who speak Arabic or Polish will be supported with translated materials and interpreters.
-The baby's GP will be informed about their participation, but all other information will be kept confidential.

What are the possible benefits and risks of participating?
Donor breast milk is donated by screened mothers and is carefully tested and pasteurised. It's already widely used for very premature babies and is considered safe.
Some babies may not tolerate feeds well, which could cause vomiting or bloating. If this happens, doctors will adjust the feeding plan.
We don't yet know if donor milk will help these babies directly, but the study will help improve feeding practices in the future.

Where is the study run from?
North Bristol NHS Trust (UK)

When is the study starting and how long is it expected to run for?
January 2024 to August 2028

Who is funding the study?
Southmead Neonatal Unit research fund (UK)

Who is the main contact?
Dr Richard Wach, richard.wach@nbt.nhs.uk

Contact information

Type(s)
Public, Scientific, Principal investigator

Contact name
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Additional identifiers

Clinical Trials Information System (CTIS)
Nil Known

Integrated Research Application System (IRAS)
353001

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
R&D 5585

Study information

Scientific Title
A randomised controlled trial to investigate whether in moderate and late preterm infants (33-35 weeks gestation) using supplementary donor breast milk versus formula for the first 5 days as a bridge to breast milk feeding improves exclusive breast milk feeds on discharge.

Acronym
BRIDGE Feed Study

Study objectives
The hypothesis is that supporting exclusive breast milk feeds by supplementing mother's own milk (MOM) with donor breast milk (DBM) in the first 5 days (study group) compared with supplementing MOM with formula (control group), will improve exclusive breast milk feed rates at discharge.

Ethics approval required
Ethics approval required

Ethics approval(s)
approved 17/07/2025, South Central - Berkshire B Research Ethics Committee (2 Redman Place, Stratford, E20 1JQ, United Kingdom; +44 207 104 8029; berkshireb.rec@hra.nhs.uk), ref: 25/SC/0168

Study design
Multi centre randomized parallel open controlled superiority trial

Primary study design
Interventional

Study type(s)
Prevention, Quality of life, Treatment

Health condition(s) or problem(s) studied
Encourage breast milk feeds in moderate to late preterm infants (33 to 35 week gestation).

Interventions
This is a randomised, controlled, superiority trial. The intervention product is donor breast milk. The control will be formula milk. All infants born at 33 weeks to 35 weeks gestation at Southmead and Bath will be assessed for eligibility. Women will be approached by the research team prior to delivery or shortly after delivery before any supplementary feeds are given. If consent is provided, the infant will be randomised to receive either standard care (supplementing mother's own milk with formula) or exclusive breast milk feeds (supplementing mother's own milk with donor breast milk) from birth for the first 5 days of feeds. Mother's own milk will be used preferentially, and supplement feeds only given if insufficient Mother's own breast milk. The amount of donor breast milk or formula will depend on amount of Mother's own breast milk available and will vary with each feed.

The mother will be randomised on a 1:1 allocation ratio utilising REDCap randomisation module. Infants from multiple pregnancies will therefore be in the same arm of the trial.

The fluid management (daily volume of fluid, the volume of feeds and whether additional supplementation with intravenous fluids is required) and the decision to commence enteral feeds and the frequency of feeds will be decided at the discretion of the clinician depending on the clinical condition.

Data will be collected until discharge and includes demographic data, invasive procedures, feed information, health outcomes, length of stay, and feeding at discharge (primary outcome). The mother's will complete short questionnaire at discharge and at 6 weeks, 3 and 6 months past their due date. The questions will include health care visits including admissions to hospital, type, and method of feeding and intention of type and method of feeding. The questionnaires will be administered by telephone conversation, email or face-to-face. There will be no additional hospital visits.

Intervention Type
Other

Primary outcome(s)
Exclusive breast milk feeding on discharge from neonatal care measured using patient records

Key secondary outcome(s))
Measured using patient records:
1. The amount of donor breast milk and formula required to supplement mother's own milk in the first 5 days.
2. Exclusive breast feeding at discharge, 6 weeks, 3 months and 6 months corrected age
3. Feed tolerance (the time taken to reach full feeds)
4. Invasive interventions (intravenous access) during hospital stay
5. Health outcomes related to prematurity at discharge
6. Length of stay

Completion date
01/08/2028

Eligibility

Key inclusion criteria
1. Infants born 33 weeks +0 days to 35 weeks +6 days gestation.
2. Randomised prior to introduction of supplementary enteral feeds.
3. Infants requiring respiratory support or other medical support can be included at the discretion of the clinician caring for the infant
4. Singleton or multiple births
5. Mother intends to breast feed
6. The mother must consent for use of Donor Breast Milk (DBM)

Participant type(s)
Patient

Healthy volunteers allowed

No

Age group
Neonate

Lower age limit
0 days

Upper age limit
5 days

Sex
All

Key exclusion criteria
1. Known congenital abnormalities of gastrointestinal tract
2. Abnormalities that make enteral feeding unsafe e.g. metabolic condition
3. Those who qualify for DBM under present guidelines (birth weight <1500g, reverse diastolic flow on antenatal doppler)
4. Mother has no intention to breast feed
5. Mother declines use of Donor Breast Milk
6. Received any formula feed prior to randomisation
7. Consenting mother is under the age of 16
8. Unlikely to remain at recruiting NICU for duration of intervention (5 days)

Date of first enrolment
01/09/2025

Date of final enrolment
01/02/2028

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
North Bristol NHS Trust
Southmead Hospital
Southmead Road
Westbury-on-trym
Bristol
United Kingdom
BS10 5NB

Study participating centre
Royal United Hospitals Bath NHS Foundation Trust
Combe Park
Bath
United Kingdom
BA1 3NG

Sponsor information

Organisation
North Bristol NHS Trust

ROR
https://ror.org/036x6gt55

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Southmead NICU research fund (B01536 Bridge Study Trial)

Results and Publications

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