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Human milk, nutrition, growth and breastfeeding (Hummingbird)

Submission date
14/04/2021

Recruitment status
No longer recruiting

Registration date
04/05/2021

Overall study status
Completed

Last Edited
08/03/2023

Condition category
Pregnancy and Childbirth

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

Plain English summary of protocol

Background and study aims
Mother's own breast milk is recommended for all preterm babies. However, it is very common that some mothers may not express enough. This means there may be a shortfall in breastmilk available. This is very common and more than half of all preterm infants will need to receive something other than their own mothers' breastmilk milk at some point in time. In this situation either formula specially designed for preterm babies or pasteurised donor human milk from a donor milk bank may be used to top-up any shortfall in mother's own milk. There is wide variation in the use of each option in different hospitals in the UK.

Doctors that recommend formula top-ups believe this benefits growth because formula has a consistent composition and a higher amount of nutrients. A recent large study in Canada showed that donor human milk did not improve brain outcomes when the babies were older. Donor human milk must be pasteurised (heat treated to destroy bacteria that might cause infection) and is therefore different to mother's own milk. Some doctors prefer donor human milk because they believe it is easier to tolerate and digest than formula milk. However, the largest study of donor human milk (conducted in the Netherlands) showed no difference in feeding complications or infections compared to using formula milk to make up any shortfall in the first 10 days. Donor human milk use is common in the UK but many hospitals do not use it. Donor human milk costs much more than formula milk.

In our hospital neonatal unit, we offer donor human milk to all preterm babies when they are first born if parents wish. However, we do not know how long we should keep using it for. In some hospitals, donor human milk is only given until full milk feeds (150ml/kg/day) are established. In other hospitals, the use of donor human milk is continued if the mother wishes to keep providing breastmilk. We would like to find out if the duration of donor human milk use affects baby's growth and how long they receive breastmilk for.

The purpose of this study is to find out if there are differences in feeding and growth in preterm (premature) babies that are given donor human milk. Donor human milk is given if there is a shortage in the supply of mother's own milk. The information from this study will add to information from other studies to improve understanding of the best way to feed preterm babies.

Who can participate?
Babies who are born before 33 weeks gestation or weigh less than 1.5kg at birth and their parents agree to give them donor human milk where there is any shortfall in supply of mother's own breastmilk.

What does the study involve?
When there is a shortfall in mother's own milk supply, babies will receive donor human milk. Half the babies will receive donor human milk as standard practice until they are tolerating full milk feeds (standard treatment group). After that we will use a preterm infant milk formula to make up any shortfall as standard practice. The other half will keep receiving donor human milk until 36 weeks corrected age as long as mother is still providing her own breastmilk. Babies who join the study have an equal chance of being in either group. This is done through a process called randomisation where information about the baby (gestation and twin status) are entered into a computer which randomly allocates a baby to one or other diet (donor human milk just to full feeds or longer). The computer programme aims to make sure that at the end of the study there are approximately equal numbers of infants receiving each diet in the study (~50-60 per group). We will also ask all mothers to complete a short (2-3 mins) questionnaire about breastfeeding and their feelings or symptoms of postnatal depression on two occasions. A small group of parents will be asked to take part in more detailed interview about feeding in the unit.

What are the possible benefits and risks of taking part?
We hope the study results will help to improve the way in which preterm babies are fed. The results may also help inform future decisions about the uses, costs and possible benefits of different products. Information we get from the questionnaires may be useful in working out what sort of support is available for mothers. We do not think there are any risks to taking part in the study because when there isn’t enough mother’s milk, formula or donor human milk are already routinely used as top-ups.

Where is this study run from?
Newcastle upon Tyne Hospitals NHS Foundation Trust (UK)

When is the study starting and how long is it expected to run for?
April 2021 to July 2023

Who is funding the study?
All costs will be covered by Newcastle Neonatal Research Team at Royal Victoria Infirmary, Newcastle upon Tyne Hospital NHS Foundation Trust. There are no external funding sources.

Who is the main contact?
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Contact information

Type(s)
Scientific

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

Integrated Research Application System (IRAS)
281071

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
IRAS 281071

Study information

Scientific Title
Human Milk, Nutrition, Growth, and Breastfeeding Rates at Discharge: The Hummingbird Study

Acronym
HUMMINGBIRD

Study objectives
To evaluate whether continued use of donor human milk (DHM) in preterm infants when there is a shortfall in mother's own milk (MOM) supply impacts on breastfeeding rate at discharge.

The primary hypothesis is that continued use of donor human milk to make up any shortfall in breastmilk supply until the pre-discharge period will increase breastfeeding rates at hospital discharge more than only using donor human milk until full milk feeds are established.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 06/04/2021, East Midlands - Nottingham Research Ethics Committee 2 (The Old Chapel, Royal Standard Place, Nottingham, NG1 6FS; +44 (0)207 104 8169; nottingham2.rec@hra.nhs.uk), ref: 21/EM/0041

Study design
Single-centre interventional open-label randomized controlled trial

Primary study design
Interventional

Study type(s)
Other

Health condition(s) or problem(s) studied
Nutrition in preterm infants

Interventions
All mothers in the Neonatal Unit are encouraged and supported to provide as much of their own breast milk (mother's own milk, MOM) as possible. When there is insufficient MOM to meet infants needs, it is called shortfall.

The Hummingbird study is designed to compare two clinical dietary approaches, both of which are routinely used in the UK, by comparing the use of donor human milk (DHM) to make up any shortfall in mother's own milk (MOM) until full feeds (control) to that of using DHM for a longer duration up to the pre-discharge period (intervention).

Infants will be enrolled on the study in the first seven days of life provided they have not been exposed to preterm formula and the mother wishes to express breastmilk after birth. Parents of infants will be consented and infants will be randomised into one of two dietary strategies where the duration of DHM use differs. The study is not blinded. Infants will be randomised using a secure, password protected online web randomisation programme (www.sealedenvelope.com) using random permuted blocks and stratification. Stratification will use the following two strata: gestation (<28 weeks yes/no), and twin/triplet status (yes/no). Twins and triplets will be allocated to the same trial arm.

Mothers who choose or are unable to continue providing MOM may do this at any point in time after they have started. Because this study is designed to impact breastfeeding at discharge, infants in the intervention group will only continue to receive DHM if their mother is still expressing breastmilk. Where the infant has not received any mother’s own breastmilk for one week, or where the mother has told clinical staff she is no longer expressing, we will discontinue use of DHM, and the baby will receive standard formula milk designed for preterm infants.

1. Intervention treatment arm will use DHM to make up any shortfall in MOM until 35-36 weeks corrected age (or the initiation of breastfeeding).
2. Control (standard) treatment arm will use DHM to make up any shortfall in MOM until full feeds are achieved (tolerating 150mls/kg/day for 48 hours).

Infant data will be recorded until discharge in both control and intervention treatment arm. All infants are routinely monitored as a part of standard care on the neonatal unit. It is a routine nursing practice to record the amount of milk baby receives, whether the milk is tolerated or not and their clinical condition. Bedside clinical nurse or clinical staff also perform routine measurements: weight (3-7 times per week) and head size (once a week) and record the status on chart and an electronic data system (Badger) whilst in intensive and high dependency care. Length and other growth parameters: mid-upper arm circumference (MUAC) and mid-thigh circumference (MTC) will be measured by clinical research staff with appropriate training weekly.

A mixed methods approach will be used to determine maternal breastfeeding self-efficacy expression. Mothers will be asked to fill in a validated questionnaire – the Breastfeeding Self-

efficacy Scale – Short form (BSES-SF) at two time points - between 5-10 days of age and again at 35-36 week of corrected gestation or prior to discharge if sooner. The BSES-SF scores will be used to identify women in the top and bottom quartiles of scores and invite up to 10 women per trial group to take part in a qualitative tape-recorded interview. A topic interview guide based on the questions on the BSE-SF will be developed. Interviews will be conducted by a single member of the research team shortly before or after hospital discharge. A consent for parents to keep in touch after discharge will be sought in order to share results and consider if longer term follow up is helpful.

Data will be analysed for all infants using an intention-to-treat approach, but the additional analysis will be performed only using breastfeeding outcome data for the first twin enrolled. Qualitative tape-recorded interviews will be transcribed and analysed using thematic analysis.

Intervention Type
Supplement

Primary outcome(s)
Breastfeeding (or a mother who is still expressing breastmilk) at 36 completed weeks of gestation or discharge if this is earlier (yes/no) measured using patient records

Key secondary outcome(s))
Measured using patient records unless otherwise stated:
1. Growth – measured weekly: weight, length, head circumference, MUAC and MTC: absolute changes (g/kg/day and mm/week) and change in standard deviation score
2. Episodes of NEC, sepsis - confirmed and clinically suspected according to existing case definitions
3. Chronic lung disease, Retinopathy of prematurity (ROP), intraventricular haemorrhage, Cystic periventricular leukomalacia (PVL) - confirmed using existing case definitions
4. Days of intensive, high and low dependency care; age at discharge, total length of stay
5. Total volume (litres) of milk (MOM, DHM and formula) received from birth to 36 weeks
6. Age at starting a fortifier
7. Type of feeding at discharge (direct breast feeding, tube feeding etc.)
8. Maternal breastfeeding self-efficacy measured using Breastfeeding self-efficacy short form (BSE-SF), Edinburgh Postnatal Depressions Score and thematic analysis of qualitative interviews in a subset of up to 20 mothers between 5-10 days of age and again at 35-36 week of corrected gestation or prior to discharge if sooner

Completion date
31/07/2023

Eligibility

Key inclusion criteria
1. Preterm infants born at less than 33 completed weeks of gestation or less than 1500g birthweight
2. Admitted to Ward 35 (Neonatal Unit, RVI) in first week of life
3. Written informed consent from parents
4. Maternal intention to provide breastmilk after birth

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Neonate

Sex
All

Key exclusion criteria
1. Parents unwilling to accept donor human milk
2. Major congenital or life-threatening abnormalities
3. Inability to randomise within 7 days of birth
4. Exposure to formula milk product prior to randomisation

Date of first enrolment
15/05/2021

Date of final enrolment
30/04/2023

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Royal Victoria Infirmary
Newcastle Hospitals NHS Foundation Trust
Richardson Road
Newcastle upon Tyne
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NE1 4LP

Sponsor information

Organisation
Newcastle upon Tyne Hospitals NHS Foundation Trust

ROR
https://ror.org/05p40t847

Funder(s)

Funder type
Other

Funder Name
Investigator Initiated and funded

Results and Publications

Individual participant data (IPD) sharing plan
All data generated or analysed during this study will be included in the subsequent results publication

IPD sharing plan summary
Other

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	protocol	07/03/2023	08/03/2023	Yes	No
HRA research summary			26/07/2023	No	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes
Study website	Study website	11/11/2025	11/11/2025	No	Yes