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SUPFOR breast milk study: a randomised controlled trial in preterm infants receiving expressed breast milk comparing the use of breast milk fortification versus supplementation using a preterm formula

Submission date
11/05/2007

Recruitment status
No longer recruiting

Registration date
04/07/2007

Overall study status
Completed

Last Edited
02/02/2017

Condition category
Nutritional, Metabolic, Endocrine

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

Plain English summary of protocol

Background and study aims
Breast milk is the best milk to give to preterm babies when they are first ready to receive milk, and breast feeding may also be the best milk to give them when they are ready to go home. However, between now and when they are ready for home, we know that your baby will need some extra energy, protein and vitamins to help him/her grow adequately. To give your baby these extra nutrients, our standard practice would be to give your baby a combination of breast milk and a special formula designed for preterm babies so they would usually get half and half. An alternative would be to give your baby all his/her milk as breast milk but add some extra nutrients using a fortifier. This comes as a powder which we simply add to the breast milk before giving it. We do not know which is the best option for babies like yours, and this study is trying to help find out why. Although it might seem more logical to add a fortifier, there are concerns that this may disturb the delicate blend of breast milk. On the other hand, supplementing with a preterm formula milk may mean we dont give as much breast milk early on as you would like.

Who can participate?
Preterm babies (less than 35 weeks gestation) receiving maternal breast milk.

What does the study involve?
If you are happy to take part we will open a sealed envelope which will tell us whether to give your baby breast milk plus formula or to use a fortifier. The envelopes have been prepared in a random order by a computer so we do not know which one your baby will get until we open it. There is a 50-50 chance that your baby will receive fortifier or formula supplementation. Your baby will then only be fed by that option until they are ready to go home. During the study we will measure your babys weight and length every week. Your baby will only have blood tests if these are decided to be necessary by the doctors looking after your baby i.e. this study does not involve extra blood tests or investigations. Most preterm babies like your will need their bloods

checking about once a week, or more often if they are not well. If you change from providing breast milk, or there is not enough breast milk is available we will use the most appropriate formula available to make up the shortfall.

When your baby is ready to go home we will ask you a few short questions on how you think the study went. We will keep in contact with you by phone after discharge to see how long you continue to breast feed (if you have decided to continue) and when you decide to wean your baby (start solids). If your baby needs to see a doctor after discharge this would take place in the normal way. We will make sure you know this before you go home.

What are the possible benefits and risks of participating?
We hope that both ways of feeding your baby will be successful but we do not know for sure which is best. We hope that the information we get from this study will help us look after babies like yours better in the future. As far as we are aware there are no significant risks associated with the study. The study conforms to internationally recommended guidelines. Both formula and fortifier are already widely used in other units. Because both these methods of feeding are already being widely used we do not believe that taking part in this study will harm your baby.

Where is the study run from?
Royal Victoria Infirmary, Newcastle upon Tyne, UK.

When is the study starting and how long is it expected to run for?
The study ran from April 2006 to August 2007.

Who is funding the study?
The Tiny Lives Fund Community Foundation (UK).

Who is the main contact?
Dr ND Embleton
Consultant Neonatologist, Ward 35 Special Care Babies, RVI
Contact number +44 (0) 191 282 5156

Contact information

Type(s)
Scientific

Contact name
Dr Nicholas Embleton

Contact details
Newcastle Neonatal Service
Royal Victoria Infirmary
Newcastle upon Tyne
United Kingdom
NE1 4LP

Additional identifiers

Protocol serial number

2004/044

Study information

Scientific Title
SUPFOR breast milk study: a randomised controlled trial in preterm infants receiving expressed breast milk comparing the use of breast milk fortification versus SUPplementation using a preterm FORmula

Acronym
SUPFOR

Study objectives
The use of a Breast Milk Fortifier (BMF) compared with supplementation using a preterm formula will result in improved growth without an increased incidence of biochemical abnormalities or adverse effect. The use of a BMF will also result in greater parental satisfaction and improved duration of breast feeding.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Newcastle and North Tyneside Local Research Ethics Committee, 17/03/2004, ref: 2004/044

Study design
Prospective randomised controlled trial in in two neonatal units

Primary study design
Interventional

Study type(s)
Treatment

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

Interventions
Groups are minimised on:
1. Growth retarded less than 10 cm
2. Multiple pregnancy
3. Gestation greater than 31 weeks

Interventions:
Formula supplement (control): 50% of total enteral feeds are provided by a low birth weight formula. We are using Nutriprem (Cow & Gate, Nutricia, Trowbridge, UK) and the intervention continues until initial hospital discharge. Follow up finishes then.

Fortifier arm (intervention): fortifier is added to all enteral breast milk feeds until hospital discharge. Follow up finishes then.

Intervention Type
Other

Phase
Not Specified

Primary outcome(s)
1. Weight gain (g/day) during initial hospital stay, measured three times a week
2. Length gain (mm/week) and head growth (mm/week) during initial hospital stay, measured once a week
3. Duration and amount of breast milk provided, measured daily

Key secondary outcome(s))
1. Maternal satisfaction, measured weekly and then at discharge
2. Incidence of abnormal biochemistry, measured when samples are taken - usually once a week

Completion date
31/08/2007

Eligibility

Key inclusion criteria
1. Preterm infants (less than 35 weeks gestation)
2. Receiving maternal breast milk

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Child

Sex
Not Specified

Key exclusion criteria
Infants who have already received fortification or supplementation (except where this was used in place of inadequate breast milk supply).

Date of first enrolment
01/04/2006

Date of final enrolment
31/08/2007

Locations

Countries of recruitment

United Kingdom

England

Study participating centre
Newcastle Neonatal Service
Newcastle upon Tyne
United Kingdom
NE1 4LP

Sponsor information

Organisation
Newcastle Hospitals NHS Trust (UK)

ROR
https://ror.org/05p40t847

Funder(s)

Funder type
Charity

Funder Name
The Tiny Lives Fund Community Foundation (UK) - approval granted on the 18/07/05

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes