COLLABORATE
Improving newborn care together

THE COLLABORATE STUDY
Parent Information Leaflet Part 1

A UK study to assess the effect of common feed types in reducing serious health issues in preterm babies born less than 29 weeks gestational age

The COLLABORATE Study
We would like to invite your baby to take part in COLLABORATE, a UK-wide study to improve the care given to babies born preterm, less than 29 weeks gestational age. Please take time to read this leaflet carefully and decide whether you would like your baby to take part. Feel free to discuss the information with others and ask us if anything is not clear.

What we are trying to find out
We want to find the best way to feed babies born less than 29 weeks gestational age. Milk from a baby's own mother is the best feed for all babies as in addition to nutrition, this contains substances that protect against infection and help promote good brain development. However, as babies born less than 29 weeks are unable to suckle at the breast, their mothers are encouraged to express milk. Expressing enough milk can be difficult, therefore, a mother may not be able to express enough, though often this is only for a brief period. There are two options to make up any shortfall; both are used in the UK and around the world. These are:

- Formula made specifically for preterm babies
- Donated breast milk from another mother, heat-treated for safety (pasteurised)

There are two questions that need answers:

1. If there is not enough milk from a baby's own mother, should we use preterm formula or pasteurised donor milk?
2. Is it necessary to add extra protein and carbohydrate to breast milk?

This neonatal unit is helping find answers to [question 1/question 2/both questions].

What happens at present?
Some neonatal units use preterm formula and some use pasteurised donor milk if there is not enough own mother's milk. Some neonatal units routinely add extra protein and carbohydrate to breast milk, while others do not.

Why is this study needed?
This study is needed because we do not know whether preterm formula or pasteurised donor milk is better if a top-up is needed, or if extra protein and carbohydrate should always be added to breast milk. These uncertainties are why there is so much variation in practice.

Some information about preterm formula and pasteurised donor milk
Preterm formula:

- Is made from cow's milk under strict safety rules to international standards
- Provides vitamins and essential minerals
- Lacks the protective factors that are present in milk from a baby's own mother
- Provides consistent nutrition
- Some doctors think that because preterm formula is made from cow's milk it might increase the risk of a gut condition called necrotising enterocolitis (NEC) which can sometimes be serious

Pasteurised donor milk:

- Is donated to a milk bank by mothers who have been screened for health and lifestyle, and is heat-treated (pasteurised) for safety
- Requires the addition of vitamins and minerals
- Loses protective factors during heat treatment
- Has very variable nutrition hence some neonatal units add extra protein and carbohydrate as a powder made from cow milk
- As the protein and carbohydrate powder is made from cow milk some doctors believe this might increase the risk of NEC
- Other doctors worry that adding extra protein and carbohydrate may provide too much nutrition and have harmful effects on health and development

How will we find the answers?
At present, babies receive what their neonatal unit thinks is best; if there isn't enough milk from a baby's own mother, some get preterm formula, and some get pasteurised donor milk as top-ups.

In the UK today, during their neonatal unit stay, about one third of extremely preterm babies receive some pasteurised donor milk and about two-thirds receive some preterm formula in addition to their own mother's milk. Because the best approach is unknown, in COLLABORATE, the choice will be made using a computer programme that ensures every baby has an equal chance of receiving either option. This is called randomisation.

To get a reliable answer to these important questions we will need around 3000 babies to take part in the COLLABORATE study. Overall, half of the babies that take part will have preterm formula, and the other half will have pasteurised donor milk if there isn't enough milk from their own mother. The study will take about two and a half years and will end these longstanding uncertainties.

Will my baby benefit from taking part?
The decision of which option each baby will receive will be made fairly and equally by randomisation. All feeding options used in this study are already used in UK hospitals.

If your baby takes part, they may not directly benefit themselves but will help improve the care of preterm babies in the future. However, participants in randomised studies like COLLABORATE often have better outcomes than equivalent patients who do not take part; this is called “inclusion benefit”.

Deciding whether you would like your baby to participate

You are entirely free to decide whether you wish your baby to participate. You can decide whether this is only in the first part of COLLABORATE (preterm formula or pasteurised donor milk if a top-up is needed), only in part two (extra protein and carbohydrate added routinely to breast milk), or both parts. If you wish your baby to take part in the study, please also read **Part 2** of this information sheet.

If you decide not to take part, your baby’s care will remain the same in every way other than that the choice of supplemental feed, should this be needed, and whether to add extra protein and carbohydrate to breast milk, will be recommended by the neonatal unit and not assigned by randomisation which is the way to give every baby a fair and equal chance of receiving either option.

What will happen if my baby takes part?

In the neonatal unit: If you decide you would like your baby to take part in either or both components, you will be asked to consent verbally, and this will be recorded in your baby’s medical notes and study records. A card will be attached to your baby's incubator or cot to remind everyone they are taking part in COLLABORATE. In all other respects, your baby will receive all the care they would normally have as usual.

We will obtain most of the information needed for COLLABORATE from your baby’s routine records that are stored in the National Neonatal Research Database. You will have received an information leaflet about this when your baby was admitted to the neonatal unit. We will also record the results of some routine blood tests. Your baby’s participation in COLLABORATE will be noted in their discharge summary which is sent to your general practitioner.

After discharge: When your baby is around 2 years you will be sent a questionnaire for you to complete as part of routine care that provides information about their development. The questionnaire can be completed on a mobile phone, tablet, or laptop. Your hospital will help you complete the questionnaire if you wish.

You may find also it helpful to watch these videos

The COLLABORATE Study	The National Neonatal Research Database	What randomisation means

If you have any questions, please speak with a member of neonatal unit staff.
Thank you for reading this leaflet.

Local Contacts

Principal Investigator
<Name and contact details>

Lead research nurse:
<Name and contact details>

<Insert PALS Name>: <Insert contact details>

Website: https://www.imperial.ac.uk/neonatal-data-analysis-unit/collaborate/