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FEED1 – Fluids Exclusively Enteral from Day 1

Participant Information Sheet

Version 1.1 16 Aug 2019

IRAS Project ID: 266702

You are invited to take part in our research study

- This information sheet is to make sure you understand why the research is being done and what it will involve for you and your baby/babies if you decide to take part.
- Please take time to read this information. Talk to others if you wish, and ask if you would like more information.
- It is entirely up to you whether or not you take part in this study. If you agree to take part, you are free to withdraw at any time without giving a reason. If you choose not to take part, your baby's/babies' care will continue in the normal way.
- Please ask us (the research team) if there is anything that is not clear or if you would like more information.

A summary of the study

- Babies who are born early are currently fed small amounts of milk through a tube into their stomach, with additional nutrition through a drip into their veins. For the purpose of this study, we will refer to this method as "gradual milk feeds".
- We do not know if it would actually be better for the long term health of babies born between 30 and 33 weeks to be fed full milk feeds from the first day of life instead.
- We want to know whether starting babies on full milk feeds rather than gradually increasing their milk feeds will reduce the number of days they need to stay in hospital.
- To help us understand more, we are comparing two different ways of feeding these babies: **(1) gradual milk feeds (usual care) and (2) full milk feeds**
- We will collect data until your baby is discharged from hospital.
- We will send you a questionnaire to complete once your baby reaches 6 weeks corrected age (6 weeks after their due date).
- We may contact you again (with your permission) up until your baby turns 2 years of age to see how your baby is doing.
- If you take part in the study and have given birth to more than one baby, each baby will be fed in the same way, provided that they are eligible to join the study.

Contents

How to contact us

Contact details of your local care team

<INSERT CONTACT DETAILS HERE>

1. What is the purpose of the study?

In the UK around 8 in 100 babies are born prematurely, and around 12% of these are born between 30 and 33 weeks.

Babies who are born early cannot feed for themselves and are given small amounts of milk through a tube into their stomach. These babies are also given additional nutrition through a drip into their veins (intravenously or IV). The amount of milk given is slowly increased until they are fully milk fed and no longer have the need for any additional nutrients. For the purpose of this study, we will refer to this method as "gradual milk feeds".

In the past, premature babies have not been started on full milk feeds because of concerns of a serious bowel disease called Necrotising Enterocolitis (NEC), however, evidence is building to suggest that in premature babies who aren't too poorly, larger milk feeds can be successfully given without increasing the risk of NEC, and might also reduce the risk of severe infection.

We are trying to find out the best way to feed babies born between 30 and 33 weeks to keep them healthy in the long term. We want to know whether starting babies on full milk feeds rather than gradually increasing their milk feeds will:

- Reduce the number of days they need to stay in hospital
- Reduce the risk of infection
- Allow the mother to be more involved in caring for the baby
- Increase parent-infant bonding
- Promote and encourage breast feeding from an earlier stage
- Make more space in the hospital for other sick babies
- Reduce the costs to the parents and to the NHS

To answer these questions, we need to conduct a large study to compare full milk feeds and gradual milk feeds. Babies will be fed by one or the other method described below:

Group 1: Full milk	Group 2: Gradual milk (usual care)
Starting at a minimum of **60ml** of milk per kg of the baby's weight each day	Starting at a maximum of **30ml** of milk per kg of the baby's weight each day
No supplementary IV fluids/nutrition	A minimum of 30ml added IV fluids/nutrition per kg of the baby's weight

2. What milk will my baby receive?

Whether or not you take part in the study, you will choose the type of milk your baby will be given after talking with the doctors and nurses. Your breast milk is the best milk for your baby. Your midwife, nurses, and doctors will support you to express milk for your baby. If you choose not to use expressed milk or if your milk takes time to come in for the first few days, the doctors and nurses will discuss other options (such as formula milk) that can also be used during the study.

3. Why have I been invited?

You have been invited to take part in this study as you are either in preterm labour, have a planned delivery at 30-33 weeks, or your baby has been born at 30-33 weeks of pregnancy.

To help us to answer our research question, we are aiming to involve 1,770 mothers with babies born between 30-33 weeks in the study.

4. Do I have to take part?

It is up to you whether or not you join the study. We will talk to you about the study and go through this information sheet. If you agree to take part, we will then ask you to sign a consent form. If you have just given birth then you may have already given your consent verbally and you will be asked to sign a consent form at a later time when it is more convenient for you. You are free to withdraw at any time, without giving a reason. This will not affect the standard of care you or your baby receive.

5. What would taking part involve?

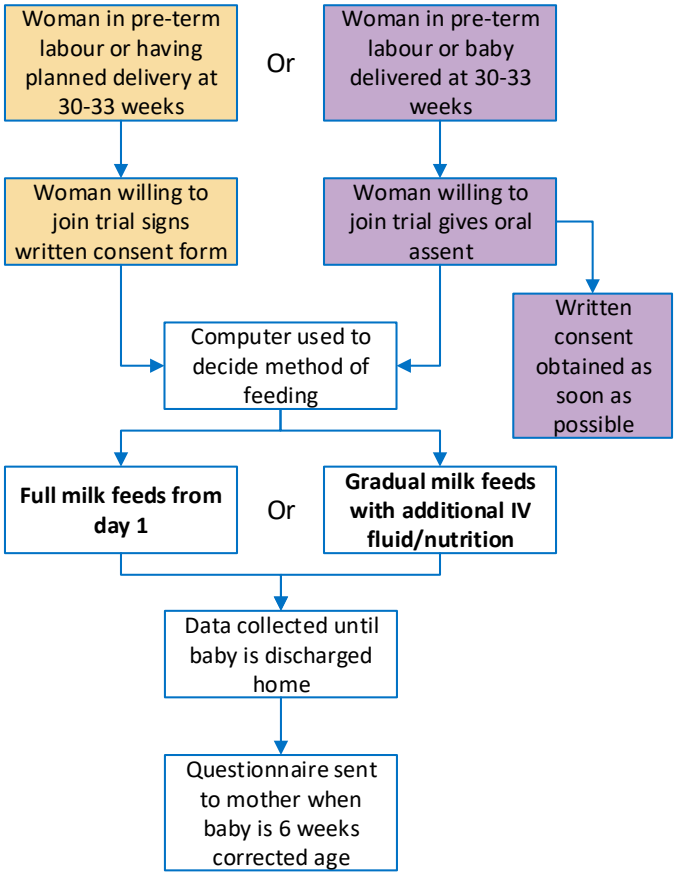
If you have been approached to take part in this study before giving birth, we will ask you to sign a written consent form. If you have just given birth, you will have already confirmed verbally that you wish to take part in the study, and you will be asked to sign a written consent form at a more practical time. If you are in labour then you may be asked to sign a written consent form or give confirm verbally depending on how you are feeling.

The decision as to which feeding group your baby will be in is not up to any individual, but is selected by a computer; you will have an equal chance of being in either of the two groups. Should you give birth to more than one baby, it is you who will be allocated to the group, and therefore your babies will be in the same group receiving the same feeding method.

Your baby will then be fed either full milk feeds or gradual milk feeds; the rest of your baby's care will follow your

hospital's usual practice.

The flowchart below shows what will happen if you decide to take part in the study.



Data such as daily feeding logs, any infections and your baby's measurements (height, weight and head circumference) will be collected until your baby is ready to go home.

Whichever group you are in, an online questionnaire will be sent to you to complete when your baby reaches 6 weeks corrected age. If you do not have access to email then a copy of the questionnaire can be sent to you by post.

With your permission, we would like to maintain contact with you as we may wish to find out how your baby is doing when they reach 2 years of age.

6. What are the possible benefits of taking part?

We do not know if taking part in the study will benefit you or your baby directly, but by doing this study we are hoping to find the best way of feeding preterm babies which may help to guide the care of premature babies in the future.

7. What are the possible disadvantages and risks of taking part?

If your baby is in the full milk group, they will be given milk from the first day. This amount of milk may be difficult for your baby to tolerate and they may vomit and/or develop bloating. If this happens the doctors and nurses caring for your baby will decide what is best for your baby and may give smaller amounts of milk more frequently or reduce the amount of milk. There may be benefits from full milk from day 1, such as reducing infections and the need for drips associated with IV feeding in the gradual milk group.

8. What if there is a problem?

All babies will be monitored extremely closely throughout the study by the hospital staff. If your baby is unwell or is struggling with full milk feeds, the doctor will discuss this with you and help you decide whether to continue to feed your baby according to the study. Your baby will continue with other IV medication such as antibiotics if required.

If you have concerns or questions about any aspect of this study, you should ask to speak to the local researchers. Their contact details are at the front of this sheet.
If any questions remain you can contact the study coordinating centre:

Feed1@nottingham.ac.uk
<contact telephone number to be inserted>

If you remain unhappy and wish to complain formally, you can do this through the NHS Complaints Procedure via the Patient Advisory and Liaison Service (PALS)

<insert Local PALS details>.

In the event that something does go wrong and you are harmed during the study, there are no special compensation arrangements. If you are harmed and this is due to someone's negligence then you have grounds for a legal action for compensation but you may have to pay your legal costs. The normal NHS complaints mechanism will still be available to you.

9. What will happen if I don't want to carry on with the study?

You are free to withdraw at any time, without giving any reason, and without your legal rights being affected. If you withdraw then the information collected will not be erased and this information may still be used in the project analysis.

10. Will my information be kept confidential?

This study is being coordinated by Nottingham Clinical Trials Unit (NCTU). The University Hospitals of Derby and Burton NHS Foundation Trust (UHDB) is the sponsor for

this study. NCTU and UHDB will together act as joint Data Controllers for this study, this means that we are responsible for looking after your information and using it properly. NCTU and UHDB will keep identifiable information about you for 5 years after the study is finished. We will follow ethical and legal practice and all information about you will be handled in confidence.

If you join the study, some of the data collected for the study may be looked at by authorised persons from the NCTU and UHDB along with other members of the research group. They may also be looked at by authorised people from regulatory authorities to check that the study is carried out correctly. All will have a duty of confidentiality to you as a research participant and we will do our best to meet this duty.

Your rights to access, change or move your information are limited, as we need to manage your information in specific ways in order for the research to be reliable and accurate. If you withdraw from the study, we will keep the information about you that we have already obtained. To safeguard your rights, we will use the minimum personally-identifiable information possible.

You can find out more about how we use your information at https://www.uhdb.nhs.uk/dtcsu-data-privacy/ and https://www.nottingham.ac.uk/utilities/privacy/privacy.aspx

NCTU will collect information about you and you infant(s) for this research study from your/your infants medical records. This information will include your name, NHS number, contact details and health information, which is regarded as a special category of information. We will use this information to assess how your infant is doing throughout the trial and to help us to answer the research question. Your contact information will be used to help us keep in touch with you for the completion of questionnaires.

All information which is collected about you during the course of the research will be kept strictly confidential, stored in a secure and locked office, and on a password protected database. Any information about you which leaves the hospital will have your name and address removed (anonymised) and a unique code will be used so that you cannot be recognised from it. The only people in NCTU who will have access to information that identifies you will be people who need to contact you to facilitate the completion of questionnaires or audit the data collection process. The people who analyse the information will not be able to identify you and will not be able to find out your name, NHS number or contact details.

A copy of your signed Informed Consent Form will be sent to Nottingham Clinical Trials Unit for review. This is to confirm that the study is being conducted in accordance with appropriate quality standards.

With your permission, we may use NHS Digital and other central UK NHS bodies to help us keep in touch with you. We will have confidentiality and security agreements in place to make sure your details are dealt with in the strictest confidence. In addition, the anonymised information collected about you may be used to support other research in future and may be shared with other researchers. We may also use your baby/babies NHS number to collect data from the National Neonatal Research Database (NNRD) for use in this study.

Your personal data (address, telephone number) will be kept after the end of the study so that we are able to contact you about the findings of the study (unless you advise us that you do not wish to be contacted). All other data (research data) will be kept securely for 5 years. After this time your data will be disposed of securely. During this time all precautions will be taken by all those involved to maintain your confidentiality, only members of the research team will have access to your and your baby's personal data.

11. What will happen to the results of the research study?

We plan to publish the results of this study in a scientific journal and may also present the results at relevant conferences. You will not be identified in any publication. We will also send you a summary of the study results, unless you express that you would not like to receive them.

12. Who is organising and funding this study?

Derby and Burton Hospitals NHS Foundation Trust are the sponsor of this study. The study is funded by the research arm of the NHS, the National Institute for Health Research Health Technology Assessment (NIHR HTA) Programme and coordinated by the Nottingham Clinical Trials Unit.

13. How have patients and the public been involved in this study?

The method of feeding preterm babies was outlined as one of the priority areas of research into babies born

prematurely by a group of parents of preterm babies. Bliss, the UK's leading charity for babies born premature or sick, are active partners in our study. A panel of parents of preterm babies have helped to design the study and have reviewed the study documents.

14. Who has reviewed the study?

All research in the NHS is reviewed and approved by an independent group of people, called a Research Ethics Committee, to protect your interests. This study has been reviewed and given favourable opinion by <insert REC name> Research Ethics Committee.

15. What if relevant new information becomes available?

If we get new information about the feeding of preterm babies during the study, your research doctor will tell you and discuss whether you should continue in the study. If you decide not to carry on, your research doctor will make arrangements for your care to continue as normal. If you decide to continue in the study he/she may ask you to sign a new Informed Consent Form.

16. What happens when the research stops?

When the study ends, your baby will continue to be cared for by their care team. If you withdraw from the study, we will need to keep and use the data collected up to your withdrawal. We will send you a newsletter with a summary of the study findings, unless you ask us not to.

Thank you for reading, you will be given a copy of this Participant Information Sheet to keep.