Mother's Initials ☐☐☐ FEED1 Trial ID ☐☐☐☐☐☐–☐

University of Nottingham UK | CHINA | MALAYSIA

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NOTTINGHAM CLINICAL TRIALS UNIT

FEED1
FLUIDS EXCLUSIVELY ENTERAL FROM DAY 1

CLINICAL TRIAL PARTICIPANT

Patient Transfer Pack

Final Version 3.0 16 November 2022

Important Information Enclosed

This infant is enrolled in the FEED1 trial.

This pack contains everything required in order to ensure the infant's continued participation in the trial.

Participant Information – ***to be completed by <u>randomising</u> (host) hospital***	
Mother's initials	☐☐☐
Infant's date of birth	☐☐/☐☐☐/☐☐☐☐ DD/MMM/YYYY
FEED1 trial ID number	☐☐☐☐☐☐–☐
Infant's NHS number	☐☐☐ ☐☐☐ ☐☐☐☐

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Patient Transfer Pack prepared by:

Name _____

Job Title _____

Contact telephone number _____

Contact email address _____

Signature _____

Name and Address of Recruiting (host) Hospital	
Principal Investigator Name ✉ ☎	
Research Nurse Name ✉ ☎	

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1. Instructions for Randomising (host) Hospital

The randomising hospital retains overall **responsibility** for its trial participants. It is important that the relevant sections of this Transfer Pack are completed in full by a member of the team at your site before the infant is transferred. Data obtained from continuing care sites (CCS) needs to be entered by the randomising hospital. CCS do **not** have access to the CRF/Macro.

1.1. Please complete the following

☐ The Participant Information box on the first page is completed

☐ A copy of the signed informed consent form (ICF) has been prepared to send with this pack

☐ A copy of the infants CRF workbook has been prepared to send with this pack

☐ A named contact at the receiving site has been identified and this information has been passed to the trial team at Nottingham Clinical Trials Unit (NCTU): feed1@nottingham.ac.uk

1.2. Randomising information - completed by randomising (host) hospital

This patient has been randomised to receive (randomising hospital to tick as appropriate):

☐ **Intervention**: Full milk feeding from day one

☐ **Control**: Gradual milk feeding (usual care)

1.3. Most recent day of feeding - completed by randomising (host) hospital

Has the infant reached full feeds at the time of transfer? (tick if yes)	☐ **Yes**
Date of most recent day of feeding	
Current working weight (grams)	**grams**
Total milk feed volume received per day (ml)	**ml**
Volume of each type of milk (ml)	
Mothers breast milk	**ml**
Human donor milk	**ml**
Breast milk fortifier	**ml**
Preterm formula milk	**ml**
Tick if breast milk fortifier was added to breast milk	**ml**
Did the infant receive IV fluids on this day? (tick if yes)	☐ **Yes**
Tick if infant received parenteral nutrition on this day	☐ **Yes**
How many hours of IV fluids and/or parenteral nutrition did the infant receive on this day?	**hours**

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2. Details of the Transfer – Completed by Transfer Team or Receiving Hospital

Did the infant receive any feeds during the transfer?	Yes ☐ No ☐
If yes, please state the volume of each type of feed (ml) Mother's breast milk Human donor milk Preterm formula milk Term formula Tick if breast milk fortifier was added to breast milk	 _____ ml _____ ml _____ ml _____ ml ☐
Did the infant received any parenteral nutrition?	Yes ☐ No ☐
Did the infant receive any IV fluids?	Yes ☐ No ☐
Were any new cannulae inserted for the purposes of the transfer?	Yes ☐ No ☐
If yes, how many cannulae were inserted?	

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3. Instructions for the Receiving Hospital (the site the infant has been transferred to)

Website: This infant is a participant in the Fluids Exclusively Enteral from Day 1 (FEED1) trial. You can find out more about the trial here: **www.feed1.ac.uk**

The Aim: In summary, the aim of FEED1 is to investigate whether, in infants born at 30+0 to 32+6 weeks (inclusive) gestation, full milk feeds initiated in the first 24 hours after birth reduce the length of hospital stay in comparison to intravenous (IV) fluids with gradual milk feeding.

We thank you for ensuring that the infant can continue to make a meaningful contribution to the study.

Protocol: A copy of the protocol has been sent to your R&D team and is available: **www.feed1.ac.uk**

Contracts: You do not need to be set up as a full site. We are only collecting routine data. No site PI is required. Please collect data as soon as the infant is in your care. When your R&D team have confirmed receipt of the Local Information Pack (LIP) data can be transferred to the randomising hospital.

What forms do you need to complete? This pack should contain everything you need, along with a copy of the infants Case Report Form (CRF) which should be sent along with this pack. Please collect data until the infant leaves your hospital.

- Please make sure the Details of the Transfer (page 4) have been completed.

If the infant <u>has</u> reached full feeds (Page 3) all you need to do is complete the following

- Hospital Discharge Form, when the infant is discharged home (eCRF workbook: p11-15)
- Serious Adverse Events (SAEs), (in this event please email the SAE team)
- Episodes of necrotising enterocolitis (NEC), sepsis (LOI) and hypoglycaemia (in this event please email: feed1@nottingham.ac.uk)

If the infant has <u>not</u> reached full feeds (Page 3), as well as the forms mentioned above, please also

- Complete the Daily Feeding Log (eCRF workbook: starting on p4), data collection on this form can **stop** when an infant has reached 140ml/kg/day for 3 consecutive days.

Important information to complete in the Hospital Discharge Form (we can only get this from you and it is essential to the study outcomes)**:**

1. The date the baby's weight reached 1700g or above
2. The date the baby has maintained stable temperatures **for 24 hours** without temperature support such as an incubator or hot cot (i.e. please review when the baby has come out of an incubator/hot cot, and record the date 24 hours later providing their temperature has remained in the normal range)
3. The date the baby for the first time
    a. had a breastfeed without NGT top-up, without requiring a further feed in the next 3 hours **OR**
    b. completed a bottle feed

Please record this in Appendix 1 in this pack. To help you remember to collect this data, please keep this with the infant's notes.

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The randomising hospital is responsible for ensuring that trial data are obtained. Please make sure the completed CRFs are sent back to the randomising hospital.

3.1. Important Contact Information

Trial Management Team (please contact us with ANY queries)	✉ ☎	feed1@nottingham.ac.uk +44 (0) 115 82 31592
SAE reporting	✉ 🖷	NCTU-SAE@nottingham.ac.uk +44 (0) 115 74 84092

Additional Information

A serious adverse event (SAE) is any untoward medical occurrence in a patient that:

- Results in death,
- Is life-threatening (NOTE: The term "life-threatening" in the definition of "serious" refers to an event in which the participant was at risk of death at the time of the event; it does not refer to an event which hypothetically might have caused death if it were more severe.)
- Requires inpatient hospitalisation or prolongation of existing hospitalisation,
- Results in persistent or significant disability/incapacity, or
- Is a congenital anomaly/birth defect.
- Other important medical events (NOTE: Other events that may not result in death are not life threatening, or do not require hospitalisation, may be considered a serious adverse event when, based upon appropriate medical judgement, the event may jeopardise the patient and may require medical or surgical intervention to prevent one of the outcomes listed above.)

SAEs should be reported to the coordinating centre (**see section 3**) within 24 hours of becoming aware of the event using the SAE form enclosed. Please note, any event that the investigator deems to be a known complication of prematurity **does not** need reporting as a SAE.

Necrotising enterocolitis (NEC) – any episodes of Necrotising enterocolitis should be reported to the randomising hospital. The data required can be found on the 'Gut-Signs' data collection form.

NEC may be diagnosed at surgery, at post-mortem examination or clinically and radiologically using the following criteria:
At least one of the following clinical signs present:

- Bilious gastric aspirate or emesis, Abdominal distension, Occult or gross blood in stool (no fissure)

And at least one of the following radiological features:

- Pneumatosis intestinalis, Hepato-biliary gas, Pneumoperitoneum

Infants who satisfy the definition of NEC above but are found at surgery or post-mortem examination for that episode to have a "Focal Intestinal Perforation" should be coded as having "Focal Gastrointestinal Perforation", not as having NEC.

Hypoglycaemia – details of all blood glucose tests with a result of <2.2mmol/L should be recorded on the 'details of hypoglycaemia' form.

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Late-onset sepsis – any episodes of sepsis (as outlined in the below definitions for microbiologically or clinically-confirmed late-onset sepsis) should be reported to the randomising hospital. The data required can be found on the 'late-onset sepsis' data collection form.

Definition of Microbiologically-confirmed Late-onset Invasive Infection (LOS)

A modified version of the UK Neonatal Infection Surveillance Network case-definition will be used:

Microbiological culture from blood or CSF sampled aseptically more than 72 hours after birth of any of the following:

- potentially pathogenic bacteria (including coagulase-negative Staphylococci species but excluding probable skin contaminants such as diptheroids, micrococci, propionibacteria or a mixed flora
- fungi

AND

Treatment for 5 or more days with intravenous antibiotics after the above investigation was undertaken. If the infant died, was discharged, or was transferred prior to the completion of 5 days of intravenous antibiotics, this condition would still be met if the intention was to treat for 5 or more days.

There is no need to report urinary tract infection unless there is also a positive blood culture.

Definition of Clinically Suspected Late-onset Invasive Infection

This is adapted from the European Medicines Agency consensus criteria and the predictive model.

Either – absence of positive microbiological culture OR culture of a mixed microbial flora or of likely skin contaminants (diptheroids, micrococci, propionibacteria) only

AND

Clinician intent to administer intravenous antibiotic treatment for 5 or more days (excluding antimicrobial prohylaxsis) for an infant who demonstrates 3 or more of the following clinical or laboratory features of invasive infection:

- Increase in oxygen requirement or ventilatory support
- Increase in frequency of episodes of bradycardia or apnoea
- Temperature instability
- Ileus or enteral feeds intolerance and/or abdominal distention
- Reduced urine output to <1ml/kg/hour
- Impaired peripheral perfusion (impaired capillary refill time >3 seconds, skin mottling or core-peripheral temperature gap >2°C)
- Hypotension (clinician defined as needing volume or inotrope support)
- "irritability, lethargy or hypotonia" (clinician defined)
- Serum C-reactive protein levels to >15 mg/L or procalcitonin ≥2mg/ml
- White blood cells count <4 or >20 X 10^9 cells/L or platelet count <100X10^9/L
- Glucose intolerance (blood glucose <2.2 mmo/l or >10 mmol/l)
- Metabolic acidosis (base excess <-10mmol/L or lactate>2mmol/L)

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APPENDIX 1

Please keep this form with the baby's medical notes and complete the following:

1. **The date the baby's weight reached 1700g or above**

2. **The date the baby has maintained stable temperatures for 24 hours without temperature support such as an incubator or hot cot – i.e. please review when the baby has come out of an incubator/hot cot, and record the date 24 hours later providing their temperature has remained in the normal range**

3. **The date the baby for the first time**
   a. **had a breastfeed without NGT top-up without requiring a further feed in the next 3 hours OR**
   b. **completed a bottle feed**
