Continuing Care Sites

The infant being transferred to your hospital is enrolled on the BASE study.

BASE is a multi-centre, pragmatic, open-label, two-arm, parallel-group, randomised control trial, evaluating whether or not we should routinely give sodium bicarbonate when a baby has metabolic acidosis. For further information, please visit the study website: https://www.npeu.ox.ac.uk/BASE

Infants are randomised to either:

Routine use of sodium bicarbonate for episodes of metabolic acidosis

OR

No routine use of sodium bicarbonate for episodes of metabolic acidosis

The transfer pack will include a cot card that indicates which trial arm the infant has been randomised to. **Please display relevant card on infant's cot at all times during their participation in the trial and adhere to the indicated trial arm.**

GUIDANCE SHEET

This sheet provides guidance on the forms contained within the **Transfer Pack**.

In summary, please follow this guidance until the infant is discharged home or reaches 40 weeks postmenstrual age (whichever is sooner):

1. Continue with the allocated study arm
2. Complete the Daily Dosing log
3. If required, complete 'Additional Case Report Forms' – listed below
4. Inform the recruiting site when infant is discharged home, transferred or dies. Complete transfer/discharge form.
5. Securely return all completed data collection forms to the recruiting site via secure email

Please ensure your site is an approved Continuing Care site before carrying out any study related activities. Approved CC sites are listed on our website: www.npeu.ox.ac.uk/base If you are unsure or are not approved, please contact the BASE study team (base@npeu.ox.ac.uk).

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NPEU Clinical Trials Unit

OXFORD POPULATION HEALTH NPEU

The Transfer Pack

The contents of the Transfer Pack are:

- Photocopy of existing dosing log and additional blank copies
- BASE Parent Information Leaflet (will contain recruiting site research team contact information)
- BASE Incident Form
- BASE Serious Adverse Events Form
- BASE Transfer/Discharge Form
- BASE Cot Cards
- BASE Guidance Sheet: Continuing Care Sites
- BASE Guidance Sheets: Case Report Forms, Safety & Incident Reporting and Withdrawals (for your information only)
- Envelope with recruiting site's address on

Importance of NNRD data

BASE heavily relies on NNRD data, particularly for the primary outcome. Therefore, it is essential that data is as **complete** and **accurate** as possible on NNRD.

STRIVE TO: Enter clinical data on NNRD once with accuracy

Prospectively check completeness and accuracy of NNRD data (this is much more efficient than retrospective checking and completion).

Completion of Dosing Log

The Dosing Log must be completed for every day that the infant is an inpatient at your Continuing Care Site. Whenever the baby has a blood gas measurement satisfying the criteria of blood pH <7.2 with pCO2 that is low or normal for the clinical context and a low bicarbonate level, and whenever the baby is given sodium bicarbonate injection, this should be recorded on the Dosing Log.

A photocopy of the current log from the Recruiting Site is included in your Transfer Pack, along with blank copies should you need them. Detailed guidance on how to complete the Dosing Log is provided in Guidance Sheet: Case Report Forms (included in your transfer pack.

GUIDANCE SHEET

This process must be adhered to until:

- **The baby is discharged from neonatal care**

  OR

- **The baby has reached 40 weeks postmenstrual age**

(whichever is sooner)

Important: Display and adhere to trial allocation cot card (included in transfer pack).

Once completed, the Recruiting Site is responsible for entering the data on the OpenClinica database. A scanned copy of the Dosing Log should be emailed from a secure email account.

Additional Case Report Forms

Serious Adverse Event (SAE) Form

Important: SAE forms are sent straight to the BASE study team, not the recruiting site. Contact details for the BASE study team at NPEU CTU are at the bottom of the guidance sheet.

The safety reporting window for this trial will be from randomisation until discharge from neonatal care or reaching 40 weeks postmenstrual age (whichever is sooner). SAEs must be reported to the BASE study team on an SAE form as soon as possible and within 24 hours of becoming aware of the event.

Only SAEs deemed causally related to sodium bicarbonate (as assessed by the local investigator) will be reported expeditiously as an SAE.

Please refer to Guidance Sheet: Safety and Incident Reporting for detailed guidance on what constitutes an SAE and how to report them to the BASE study team.

SAEs can be reported by any member of staff. Causality assessment is required for SAEs. Guidance Sheet #: Safety and Incident Reporting states that individuals must be delegated to complete causality, however, for Continuing Care Sites, this can be completed by a medically trained doctor. Do not delay reporting the SAE whilst waiting for a causality assessment. The SAE may be sent to the BASE Study Team initially without the causality assessment. An updated form must be sent when the causality is complete.

Incident Reporting Form

Deviations from protocol, trial specific procedures or Good Clinical Practice (GCP) must be reported to the BASE study team, using the Incident and Deviation form. A scanned copy should be sent to base@npeu.ox.ac.uk.
For guidance on how to report incidents, please refer to Guidance Sheet #: Safety and Incident Reporting.

Withdrawal Form

If an infant is withdrawn from the study, please let the recruiting site know. They will need to complete a withdrawal form.

Remember: it is only considered a withdrawal if the parent has chosen to withdraw their baby from the allocated trial arm **and** has declined continued data collection. If parent agrees to ongoing data collection, this **does not** constitute a withdrawal, but a discontinuation of the allocated trial arm. As per GCP guidance, the parent does not need to specify reasons for withdrawal.
The parent can withdraw their infant from some or all of the data collection in the study. Data collected up until the point of withdrawal will be used in the study. For more information, please refer to Guidance Sheet: Withdrawals.

Transfer/Discharge Form

Please use this form when the baby leaves your hospital, e.g. transferred or the baby has died. Otherwise, please complete this form or if the baby is still an inpatient at your hospital and has reached 40 weeks postmenstrual age.

If an infant is due to be transferred to another hospital, please immediately notify the Recruiting Site (contact details can be found on the back of the Participant Information Leaflet. Once a transfer has occurred, please complete the paper Transfer Form and securely email a scanned copy to the Recruiting Site.

If you have any queries, please contact the BASE study team:

Any queries should be directed to the BASE study team during office hours (i.e. between 09:00-17:00, Monday to Friday) on 01865 289716 or email base@npeu.ox.ac.uk

GUIDANCE SHEET