Case Report Forms

GUIDANCE SHEET

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).

Overview of data collection forms:

Form	Format	When to complete
Screening log	Randomisation website	Complete monthly
Documentation of Verbal Consent form	Paper copy	When a parent has provided verbal consent for their baby to take part
Randomisation	Randomisation website	When eligibility has been confirmed and parent has provided verbal consent
Contact details form	Randomisation website	After randomisation
Trial entry form	Openclinica	After randomisation
Daily dosing log	Paper copy, then transcribed to OpenClinica	Every day after randomisation until baby is discharged or reaches 40 weeks postmenstrual age (whichever is sooner)
Transfer/discharge form	Openclinica	Infant is transferred to another hospital, discharged home, reaches 40 weeks postmenstrual age, or dies
Withdrawal/Discontinuation form	OpenClinica	Parent withdraws any time between randomisation and end of the study
Serious adverse event (SAE) form	OpenClinica	As soon as possible after site becomes aware of event defined as serious (until baby is discharged or reaches 40 weeks postmenstrual age)
Two-year follow up form	OpenClinica	When baby reaches 24 months (corrected age)
Wellbeing check	Occurs at site	Before baby's 1st and 2nd birthdays

BASE is funded by the National Institute for Health and Care Research (NIHR) Health Technology Assessment (HTA) Programme (Reference Number NIHR151086).
The views expressed are those of the author(s) and not necessarily those of the NIHR or the Department of Health and Social Care.

FUNDED BY NIHR | National Institute for Health and Care Research

NPEU Clinical Trials Unit

OXFORD POPULATION HEALTH NPEU

OpenClinica access

Electronic CRFs are completed on OpenClinica. Each site staff member requires an individual account. Please contact the BASE study team if you require an account creating (base@npeu.ox.ac.uk)

Randomisation Website access

The screening log and randomisation system is on the Randomisation Website. Each site staff member requires an individual account. Please contact the BASE study team if you require an account creating (base@npeu.ox.ac.uk)

Please see **Guidance Sheet: Randomisation** for more details about the randomisation process

Documentation of verbal consent form

Documentation of verbal consent forms will be provided in the document box. Complete when a parent has provided verbal consent for their baby to be enrolled into the study. They must be completed and signed by a delegated and trained individual. Once baby is randomised, scan and save a copy in your eISF.

Please see **Guidance Sheet: Verbal Consent** for instructions on completing the documentation of verbal consent form.

Randomisation and Contact details

Please see **Guidance sheet: Randomisation** for details of how to access the randomisation and contact details forms. Complete the contact details form as soon as possible.

Study team will use mobile number and email address to contact parents for the two-year follow up, it is therefore very important these are entered in correctly. If parents wish to update their contact details, please update the contact details form on the randomisation system.

All required fields on the contact details form will be flagged if left blank. It is possible to save despite missing data if absolutely necessary; please try to provide this missing data as soon as possible.

Trial Entry Form

Sections 1 and 2 of the Entry form on OpenClinica are completed automatically from the information entered during randomisation. Review and amend information in section 1 on OpenClinica, then complete section 3. Section 2 can never be edited.

Daily Dosing Log

This log must be completed each day after randomisation until the infant is discharged or reaches 40 weeks postmenstrual age. A paper copy should be kept by the cot side for completion. Once completed the research nurse (or delegate) will be responsible for checking the accuracy of the data and entering into OpenClinica. The paper copy should be scanned and saved in your eISF.

Completing the log

Enter the infant's details at the top and fill in the log each day after randomisation. Complete Table 1 each day, and complete Tables 2-4 when applicable.

Table 1 - records whether an infant meets the criteria for metabolic acidosis and if they received sodium bicarbonate that day.
Table 2 – records details of metabolic acidosis episode
Table 3 – records details of sodium bicarbonate infusion
Table 4 – records if infant allocated to routine use of sodium bicarbonate arm does not receive it for an episode of metabolic acidosis

Transfer/discharge form

Complete a transfer/discharge form for the following events:

- Transferred to another hospital
- Discharged home
- Reaches 40 weeks postmenstrual age
- Dies while in hospital

The PI must countersign the form on OpenClinica. This is to confirm accuracy and completeness of data relating to primary outcome in NNRD.

Some infants will have multiple transfer/discharge forms completed

If an infant is discharged home from, transfers from, or dies at a continuing care site, the recruiting site is responsible for completing the Transfer/Discharge Form(s) on OpenClinica. The continuing care site should send over completed paper/scanned copy. The PI is only required to countersign transfer/discharge forms completed at their own site, and not for forms completed at continuing care sites.

Withdrawal/Discontinuation form

Please refer to **Guidance Sheet: Withdrawals**

Serious adverse event (SAE) form

Please refer to **Guidance Sheet: Safety and Incident Reporting.** SAEs must be reported to NPEU as soon as possible, even if you do not have all the information available yet.

Continuing care sites should report SAEs directly to BASE study team, rather than recruiting site.

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Two-year follow up form

The two year follow up form will be completed by the parent when the infant is 24 months of age (corrected for prematurity). BASE study team will be responsible for contacting the parent to complete the form.

Where possible, the site should remind the parents on discharge that they will receive a 24 month questionnaire to complete by email.

Wellbeing check

The study team will send 1st and 2nd birthday cards to the infants. We will be asking sites to confirm the infant has not died before we send out the cards.

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