FAQs for Recruiting Sites

Enrolment

1. How do I enrol an infant to the study?

Go to BASE study website and click **'Randomise to BASE'** or go to https://rct.npeu.ox.ac.uk/base/login.php. You will need to login with your individual login details. Please get in touch with the study team if you require an account creating, or have any difficulty with this.

If you experience any issues with the randomisation website, please contact the BASE study team.

2. Who can assess eligibility?

Any trained individual can confirm eligibility, as long as they have been delegated this responsibility on the delegation log.

3. Can we approach parents before the eligibility criteria has been met fully?

Yes, we recommend approaching parents of babies born between 23^{+0} and 30^{+6} weeks^{+days} as early as possible to inform them about the study and obtain consent. This can even be before the baby is born. A parent friendly video is available on the BASE website, which is a good way to introduce the study to parents.

Once consent has been given, the baby can be randomised as soon as possible if they develop metabolic acidosis. Use the 'Eligible' cot card to remind staff to check for episodes of metabolic acidosis that meet the study criteria.

4. What is the consent process?

Parents must provide verbal consent for their baby to take part. They do not need to sign a consent form. Documentation of their consent must be recorded in the baby's medical notes, and filed in the eISF if they are randomised.

Consent can be obtained remotely over the phone.

5. Who can obtain consent?

Any trained individual can obtain consent, as long as they have been delegated this responsibility on the delegation log.

6. Does the BASE study team need to see evidence of consent?

Evidence of consent should be recorded on the Documentation of Verbal Consent form, which should then be filed in the baby's medical notes and in the participant's file in the eISF (if they're randomised). On the randomisation form, there is a checkbox which confirms verbal consent has been given and documented. The BASE study team does not need to receive any further evidence. The BASE research nurse will check the documentation of consent forms during site monitoring visits.

7. Is the Patient Information Leaflet (PIL) available in other languages?

Unfortunately, the study documents are only available in English. NHS translation services can be utilised as per standard care and if the clinical team deem that the parent has sufficient understanding about the study in order to provide full informed consent.

8. Can infants be enrolled into BASE and another study?

Yes, co-enrolment is generally allowed. We are not aware of any conflicting studies. Please get in touch with BASE study if you have any questions or concerns about this.

9. Who can randomise a baby?

Any trained individual can enter a baby onto the randomisation system, as long as they have:

- Completed the BASE randomisation system online training (9 minute video) and confirmed with the trial team that this has been watched and understood
- Been delegated this responsibility on the delegation log.
- Received an individual log-in to the randomisation system

We would recommend training as many members of staff as possible in how to use the randomisation system, so that no eligible babies are missed where there was no-one available with access to the system.

10. Can I recruit a baby which lives out of area?

Yes, you can recruit a baby which lives out of area. If they are due to be transferred to another hospital, please follow the usual transfer process as described in the Transfer of Infants Guidance Sheet.

11. Can babies born to under 16 year olds be included in the study?

If the parent/carer(s) is determined to be competent to understand the trial then their baby can be enrolled in the trial.

12. How will multiples be randomised?

Multiples will be randomised independently. Therefore they may not be allocated to the same trial arm.

13. How do I add an infant to the screening log? And who shall I add?

A paper screening log will be provided in the Document Box for internal use only. All completed screening entries must be entered onto the screening log section of the Randomisation website on a monthly basis.

All infants born between 23^{+0} and 30^{+6} weeks^{+days} should be screened and added to the screening log. A baby's screening log entry is complete when they are either randomised to the trial or they are confirmed to be permanently ineligible, for example:

- they satisfy at least one of the stated exclusion criteria
- their parent(s) declined
- they reach 34+0 weeks+days postmenstrual age
- they cannot be recruited because they have been transferred/discharged away from your site