

To randomise, you must be delegated to this role and have individual access to the randomisation system.

IMPORTANT: It is key for as many people as possible to have access to the randomisation system to ensure eligible babies are not missed.

Prior to randomisation, please ensure:

- Parent has provided **verbal consent** and the **Documentation of Verbal Consent form** has been completed and filed in the baby's medical notes
- **Eligibility** has been confirmed by an appropriately trained **neonatal doctor** or **nurse** as recorded on the delegation log.

Infants will be randomised to either:

1. Routine use of sodium bicarbonate infusion for episodes of metabolic acidosis

Or

2. No routine use of sodium bicarbonate infusion for episodes of metabolic acidosis

Randomising infants to BASE

Randomisation occurs through a secure web-based randomisation system hosted by the National Perinatal Epidemiology Unit Clinical Trials Unit (NPEU CTU) based at University of Oxford. There are three main stages of randomisation; randomising on system, completing contact details form, placing cot card on infant's cot and filing copy of verbal consent form in e-ISF.

First, randomise infant:

1. Go to <https://rct.npeu.ox.ac.uk> and select **BASE**. Link is also available on the study website (www.npeu.ox.ac.uk/base)
2. Login to the randomisation system using your individual login details
 - o Select site name from the drop-down list
 - o Enter username and password
3. Once you're logged in, click 'Randomise infant'
4. Complete the questions relating to eligibility and consent.

The person completing the form must be delegated for randomisation as documented on the delegation log.
5. Once you have clicked 'Complete', the **BASE study number** and **treatment arm** allocated to the infant will be displayed.

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Next, enter contact details:

Contact Details form

After an infant has been randomised, click '**Enter contact details**'. This will open up as a new window. Please enter in the parent(s) and infant's contact details.

Finally, place relevant cot card and red book sticker, and file a copy of the verbal consent form in e-ISF:

Put relevant cot card stating which treatment arm the infant is allocated to next to randomised infant's cot, so it is visible to all staff. Enter infant study number on Documentation of Verbal Consent form, and file a copy in the e-ISF (there should now be 1 copy in the baby's medical notes and 1 copy in the e-ISF).

There are BASE stickers available for site staff to put onto the infant's red book showing they are part of the BASE study. You can find these in the document box.

Entry form

Once infant has been randomised using these steps, please complete Section 3 of the trial entry form on OpenClinica. Sections 1 and 2 will have been auto-filled with the data you entered at randomisation.

If any errors were made in the data entered on the randomisation site, correct it on the Entry form.

- *Trained and delegated individuals should contact study team if in need of an OpenClinica account*

Thank you card

Before an infant is discharged or transferred away from your site, give parents of randomised infants a BASE Thank You card (provided in the Document Box). If an infant enrolled in the study dies, please give a BASE Thank You card to the parents at a time that you deem to be appropriate.

Technical support

If you experience technical difficulties or require help with the randomisation website, please contact the BASE study team using contact details below:

- During office hours: **base@npeu.ox.ac.uk, 01865 289716**
- Out of office hours (**for emergency use ONLY**): **0800 138 5451**