

## Screening in the Neonatal Unit

- Screening can be completed by any trained individual (however, final confirmation of eligibility can only be confirmed by delegated neonatal doctors or nurses).
- All babies born/expected to be born between 23<sup>+0</sup> and 30<sup>+6</sup> weeks<sup>+days</sup> of gestation inclusive should be screened for eligibility. Parents can be approached either antenatally or postnatally to discuss the study and seek verbal consent.
- Sites should use the 'Eligible' cot card for babies born between 23<sup>+0</sup> and 30<sup>+6</sup> weeks<sup>+days</sup> of gestation inclusive to ensure they are checked for episodes of metabolic acidosis that meet the study criteria. These cards can be used for babies whose parents have not yet been approached for verbal consent, those considering participation or have already provided verbal consent.
- Cards with QR codes will be provided which link directly to a BASE parent-friendly introduction video (<https://www.npeu.ox.ac.uk/base/parents/base-introduction-video>). This video is available in 5 different languages and can be utilised along with the short Introduction leaflet and full Parent Information Leaflet (PIL) at this stage to provide information about the study.
- To maximise awareness of the study, study information should be made widely available throughout the NICU in the form of BASE posters, banners and information leaflets
- To remind site staff about recruiting to BASE, we recommend putting 'Think BASE' posters next to the blood gas analyser machines and cupboards where sodium bicarbonate is stored.

The inclusion and exclusion criteria for the study are as follows:

### Inclusion Criteria:

- Babies born between 23<sup>+0</sup> and 30<sup>+6</sup> weeks<sup>+days</sup> of gestation inclusive
- Postmenstrual age less than 34<sup>+0</sup> weeks<sup>+days</sup>
- Metabolic acidosis defined as blood pH less than 7.2 with pCO<sub>2</sub> that is low or normal for the clinical context and a low bicarbonate level.
- The parent's verbal consent for the baby to participate in the trial has been documented in the baby's medical notes and Investigator Site File (ISF).

### Exclusion Criteria:

- Life-threatening condition, or significant congenital anomaly
- Inborn error of metabolism (known or under active investigation)
- Prior treatment with sodium bicarbonate *unless* in the context of cardiopulmonary resuscitation or if used as a substitute for normal saline in arterial line infusion
- Current episode of metabolic acidosis immediately follows cardiopulmonary resuscitation.

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If the parent is willing for their baby to participate and provides verbal consent, please see [Guidance sheet: Verbal consent](#) and [Guidance sheet: Randomisation](#) for more information.

## Screening Logs

The screening log is online on the Randomisation Website. A screening log entry should be added to the online system when a baby born between 23<sup>+0</sup> and 30<sup>+6</sup> weeks<sup>+days</sup> meets one or more of the following criteria:

- They satisfy at least one of the exclusion criteria and are therefore ineligible
- Their parent has declined participation
- They have reached 34<sup>+0</sup> weeks<sup>+days</sup> postmenstrual age and not had an eligible episode of metabolic acidosis or had an episode of metabolic acidosis that was missed
- They cannot be recruited because they have been transferred / discharged away from your site

Randomised babies will be added to the screening log automatically during the randomisation process.

## Varying Eligibility for the Same Baby

Neonatal staff at recruiting sites are expected to check all babies born between 23<sup>+0</sup> and 30<sup>+6</sup> weeks<sup>+days</sup> of gestation for eligibility. However, due to the nature of the eligibility criteria, it is possible that the same baby could be ineligible at one point (no episodes of metabolic acidosis) and eligible at another (when an episode of metabolic acidosis that meets the study criteria occurs).

For this reason, we do not require a screening log entry to be completed every time a baby's eligibility is assessed. A baby should only be on the screening log once.

## Uploading Screening Logs

- Once a month, enter summary data for those screened on the BASE randomisation website by visiting <https://rct.npeu.ox.ac.uk/base> logging in and choosing the screening log option.
- A copy of the BASE Screening Log that can be printed is available in the Electronic Investigator Site File (e-ISF).
- Paper logs are provided for internal use only and do not need to be submitted back to the study team, unless these have been requested for additional monitoring purposes.

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## Co-recruitment

Co-recruitment of participating babies to other non-interventional studies would generally be permitted. Co-recruitment to another interventional trial may be possible following discussion and agreement between Chief Investigators if perceived to not affect the outcome of this trial in any way.