

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⁺⁰ and 30⁺⁶ weeks^{+days} 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⁺⁰ and 30⁺⁶ weeks^{+days} 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, and those that 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 6 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 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⁺⁰ and 30⁺⁶ weeks^{+days} of gestation inclusive
- Postmenstrual age less than 34⁺⁰ weeks^{+days}
- Metabolic acidosis defined as blood pH less than 7.2 (or optionally between 7.20 and 7.25) with pCO₂ 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

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.

Optional higher pH threshold

An optional higher pH threshold has been introduced. Treating clinicians have the option to randomise a baby if they develop metabolic acidosis with a blood pH that is between 7.20 – 7.25.

A baby may only be randomised at a higher pH threshold if there is intention to treat. Once a baby has been randomised, the episode that made them eligible must be managed according to their allocated treatment arm. If the baby has been randomised to routine treatment with sodium bicarbonate, subsequent episodes may be treated with sodium bicarbonate using either the optional threshold of between 7.20 – 7.25 or the threshold of < 7.2 , based on clinician discretion.

Screening Log

The screening log is on the Randomisation Website (<https://rct.npeu.ox.ac.uk/base>). A baby should be added to the log when they are admitted to the neonatal unit.

Important: A baby must be on the screening log before they can be randomised.

Neonatal staff at recruiting sites are expected to check all babies born between 23⁺⁰ and 30⁺⁶ weeks^{+days} 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). Therefore, babies should be added to the log when first screened, and their record **updated** whenever their eligibility is assessed. Each baby should only be on the log once. Do not add them as a new entry every time their eligibility is assessed.

The screening log includes space to record whether a baby has had an episode of metabolic acidosis or been given sodium bicarbonate via arterial line during the following periods:

- Up to the point when the parent is approached to discuss the trial (or when it is decided they will not be approached)
- If parent is approached: from when the parent is approached until a consent decision is made
- If consent is obtained: from when consent is given until the baby is randomised or it is confirmed that they will never be randomised

Please aim to update this information on at least a **weekly** basis.

Once a baby on the log meets one of the following criteria, their screening log entry should be checked for completeness:

- They satisfy at least one of the exclusion criteria and are therefore ineligible
- It has been decided that their parent will not be approached to discuss participation
- Their parent has declined participation
- They have not yet been recruited and have reached 34⁺⁰ weeks^{+days} postmenstrual age
- They cannot be recruited because they have been transferred / discharged away from your site
- They have died prior to being recruited

Screening log data will be used to inform feasibility trial outcomes. Therefore, it is important that it is completed accurately and in full.

Consent for the qualitative study

If a baby's parent consents to taking part in the qualitative study, this should also be documented on the screening log. Parents can take part in this without consenting for their baby to be enrolled in the feasibility trial. Therefore, babies must also be on the screening log before involvement in the qualitative study can be documented.

Co-recruitment

Babies enrolled in the BASE observational study cannot be co-recruited to the BASE feasibility trial.

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.

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