

GUIDANCE SHEET 1: Eligibility

All infants on the neonatal unit or maternity ward requiring a lumbar puncture (LP) should be screened for eligibility. Delegated clinicians and research nurses can carry out screening and eligibility checks. Infants requiring an LP should be assessed for eligibility when they are judged to be clinically stable for LP. The team looking after the infant should assess for contraindications to LP. Refer to NICE guidance on bacterial meningitis (<https://www.nice.org.uk/guidance/cg102>) if required. Infants originally deemed clinically unstable for LP may be eligible once stable enough for LP.

Ensure that parents understand why their infant needs an LP prior to approaching them about the study.

Inclusion

Infants will be considered **eligible** for inclusion in NeoCLEAR if:

- Corrected gestational age 27⁺⁰ to 44⁺⁰ weeks inclusive
- Working weight 1000g or more
- First lumbar puncture for current indication

All eligibility criteria must be met for an infant to participate.

Where a lumbar puncture is **indicated, but is not urgent**, the infant should be considered for the trial (e.g. an apparently well infant on the postnatal ward, already on antibiotics, with raised inflammatory markers)

Exclusion

Infants will be excluded from participating in the trial if:

- Unable to be held in sitting position (e.g. mechanically ventilated, open gastroschisis)
- Previously randomised in this trial

If a lumbar puncture is clinically urgent, and waiting for trial consent would be clinically unsound, do not delay the lumbar puncture (e.g. optimising antibiotics in an infant with a high clinical suspicion of meningitis). If in doubt, discuss with the infant's Consultant.

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Infants *unable to be held in a sitting position* include those who are mechanically ventilated; have a clinical condition that makes sitting difficult; or where their condition might be compromised by sitting. *Infants should not be excluded based solely on the concern that it might be difficult to sit up a smaller infant*, as trials of sitting LP have previously included infants as small as 1000g and 27+0 weeks.

Where an infant has had a previous lumbar puncture for a different clinical indication:

- If the infant was recruited and randomised to NeoCLEAR, they would not be eligible to participate again.
- If the infant was not recruited to NeoCLEAR (either due to ineligibility or parental uncertainty) and they are now eligible, parents may be approached again for consent.

Screening Pack

Once an eligible infant has been identified, collect a Screening Pack from the Site Document Box. Give the Parent Information Leaflet to the parent(s), complete the Screening sticker and stick this in the Infant's Medical Records.

Screening Log

At least once a month, complete the screening details for your site on the Randomisation Website by visiting <https://rct.npeu.ox.ac.uk/neoclear>, entering the site login details* and completing the screening tab. Include **all infants who undergo a lumbar puncture** on the neonatal unit or maternity wards, even if they meet exclusion criteria or parents decline. Do not include any personal identifying information.

If helpful, complete the paper Screening Log found in the Investigator Site File, and transfer the information to the online Screening Log.

*Site login details are found inside the lid of the Site Document Box.