

GUIDANCE SHEET 4: LP Procedure

Lumbar Puncture Procedure

The key aspects of NeoCLEAR are the positioning of the infant and timing of stylet withdrawal. These will be determined by randomisation.

The rest of the procedure should be standardised as far as possible, to reduce other factors which might affect success (e.g. analgesia and needle type). Parent(s) may be present for the procedure at the discretion of the clinician.

A procedure is defined as a lumbar puncture involving one operator in one episode, but can include up to two attempts.

An attempt is defined as an instance of skin puncture. The needle can be readjusted after passing through the skin.

Team Members

Ensure each team member is aware of everyone's roles and responsibilities prior to the start of the procedure.

Note: all team members will have access to training videos. Research Nurses should be consulted for advice/support.

Operator

Any medical professional (usually a Doctor or Advanced Neonatal Nurse Practitioner (ANNP)) who has:

- previously performed a neonatal lumbar puncture **AND**
- received NeoCLEAR procedure training **AND**
- been approved on the Delegation Log to perform NeoCLEAR LPs

Ideally, the operator will have been nominated prior to randomisation, but the LP can proceed with another suitable operator if the nominated practitioner becomes unavailable. The operator is responsible for ensuring that the first assistant holds the infant securely and safely in the position determined by randomisation (sitting or lying) and that the stylet is withdrawn at the correct time.

GUIDANCE SHEET 4: LP Procedure

Assistants

The **assistant holding the infant (first assistant)**, may be shown by the operator how to **position and hold the infant as allocated by randomisation**.

The **second assistant** will need to:

- **Measure the time taken for the procedure** (from cleaning the skin to removal of needle at the end of all attempts).
- **Monitor the heart rate and oxygen saturation trace** and record the highest and lowest values for heart rate and lowest oxygen saturation.
- **Collect the CSF.**

If only one assistant is available, they would hold the infant, measure the time and monitor the heart rate and oxygen saturation trace, while the operator performs the LP and collects the CSF.

During **needle insertion on the first attempt**, all clinical staff present must monitor the infant's movement. The operator and an assistant will need to **agree on a movement score** and record this on the trial electronic Procedure Form or paper Procedure Log.

Trial Admin

Before procedure, the operator should:

- Check that informed consent for the procedure has been given, following GMC Good Medical Practice guidance.
- Ensure that written consent for the trial has been given, following GCP (Good Clinical Practice)
- Check that consenting parents have completed the first Parent Questionnaire. Add the study ID, parent name and questionnaire number to the front of the Questionnaire before it is placed in the Participant Pack.
- Be approved on the NeoCLEAR Site Delegation Log.
- Collect the paper Lumbar Puncture / Lab Results Log from the participant pack (or Document Box if 2nd procedure), ready for completion, or log in to OpenClinica and open the correct participant/form for electronic completion.

GUIDANCE SHEET 4: LP Procedure

Preparing for the procedure

- For term infants, where possible and not contraindicated, apply topical anaesthetic cream (e.g. EMLA® cream) 45-60 minutes before the procedure (this should be wiped off after 60 mins to reduce skin irritation, but remains effective for up to 2 hours).
- Check to which technique the infant has been allocated (see printout from randomisation). Refer to appropriate training video (www.npeu.ox.ac.uk/neoclear/clinicians/training) as necessary.
- The operator should ask a senior practitioner to supervise if needed. If still unsure, discuss with the infant's Consultant about whether to proceed with further support or whether another delegated operator should carry out the procedure.
- Identify infant and confirm with another member of staff.

Preparing the area

- Identify suitable clinical area to perform lumbar puncture.
- Ensure appropriate thermal care, use a temperature probe or radiant heater if necessary.
- A portable or mounted saturation and heart monitor must be set up and supplementary oxygen should be available.

Equipment

Provided by NeoCLEAR if not used routinely:

- Topical anaesthetic cream (term infant) – e.g. EMLA® cream or Ametop®
- Clear dressing
- Timer
- Lumbar puncture needles (22G Quincke with Stylet)
- Sucrose solution
- Dummy/pacifier

GUIDANCE SHEET 4: LP Procedure

Standard equipment (used as per local guidelines):

- Non-sterile gloves
- Up to 2ml milk or Sucrose solution (all infants, unless contraindicated)
- Pulse oximeter
- Sterile gown
- Sterile gloves x 2
- Sterile pack
- Chlorhexidine 2% with 70% alcohol cleaning solution – e.g. Chloraprep® x 3
- Sterile pots x 3 (pre-labelled 1, 2 and 3)
- Glucose container (usually sodium fluoride/potassium oxalate) if used locally
- Spray dressing (e.g. Opsite®) +/- or spot plaster
- Equipment to check blood glucose

Procedure

If the infant becomes clinically unstable, pause or abandon the procedure and record this in the notes and trial (electronic/paper) Procedure Form.

1. Clinical team wash hands and put on non-sterile gloves.
2. Undress infant, leave nappy on but pulled down slightly at the back.
3. Remove analgesic cream from infant's back and clean any visibly soiled skin with water.
4. **Connect infant to saturation/heart rate monitor.** Ensure good trace.
5. Prepare sterile trolley (open sterile pack, chlorhexidine applicators and needle).
6. Number three sterile pots and a glucose tube and loosen the lids.
7. Prepare equipment for checking blood glucose.
8. With dummy (or gloved finger) to suck on, give milk or sucrose, in small amounts, starting 1-2 minutes prior to needle insertion. Up to 2ml can be given (according to local guidelines), with the aim of consoling the infant via establishing non-nutritive sucking.
9. Identify area for needle insertion
10. The conus medullaris reaches approximately L3 in term newborns (lower in preterm).
11. The intercrystal line is sometimes perceived to intersect as high as L2/3, therefore aim for the intervertebral spaces below the intercrystal line.

GUIDANCE SHEET 4: LP Procedure

Discuss the position of the infant with the assistants and check that the

12. **operator and first assistant are happy with how they are able to hold the infant.**
13. Operator to re-wash hands and put on sterile gown and two pairs of gloves.
14. First assistant to hold the infant comfortably in sitting or lying position as determined by randomisation.
15. Second assistant to:
 - a. **start the timer at the start of skin cleaning.**
 - b. **record the highest heart rate, lowest heart rate and lowest oxygen saturations (with good trace) throughout the procedure.**
16. Operator to clean the area with chlorhexidine three times and allow at least 30 seconds for this to dry. Ensure no clothing or nappy touches cleaned area. Avoid pooling of antiseptic.
17. Operator to remove outer pair of sterile gloves.
18. Place infant onto sterile drape.
19. **First assistant to hold infant firmly in either sitting or lying position.** Spine should be straight and vertical (if sitting) or horizontal (if lying). Hips and knees should be flexed, but do not overflex the neck.
20. Operator to identify interspinous space below intercrystal line.
21. Ensure the infant is held still; consider readjusting the hold or requesting assistance with holding or comforting the infant.
22. Aiming towards the umbilicus, insert needle with stylet in place with **the bevel facing to side of the infant.** Note level of movement during needle insertion on first attempt. Advance the needle through skin and subcutaneous tissues.
EARLY STYLET REMOVAL (ESR): remove stylet **now, once through skin and subcutaneous tissue** (keep stylet in sterile area) and slowly advance the needle until cerebrospinal fluid (CSF) is visible in the hub.
LATE STYLET REMOVAL (LSR): leave stylet in place and advance the needle to **where CSF would be expected**, then remove the stylet (keep stylet in sterile area).

GUIDANCE SHEET 4: LP Procedure

GUIDANCE SHEET 4

If CSF:	Collect CSF in bottles in order: 1, 2, 3 then glucose sample (aiming for 5 drops per bottle in preterm, 8 drops per bottle in a term infant. Even 2-3 drops may be suitable for microscopy). Replace stylet and withdraw needle.
If no CSF:	Rotate bevel to face towards head. Consider withdrawing a short distance or advancing needle further (replace stylet for manipulation if late stylet removal). Massage fontanelle. Check positioning and needle angle, and review the need to withdraw to subcutaneous tissues and re-direct needle. If randomised to LSR replace stylet whilst manipulating the needle.
If frank blood:	Consider waiting to see if sample becomes clearer, try slightly withdrawing the needle, or replace stylet and withdraw the needle.
If still no CSF or frank blood only,	Prepare for second attempt. If blood is the only sample obtained after two attempts, please send to lab.

23. Ensure haemostasis.
24. Second assistant to **stop timer at the end of procedure** (removal of needle at end of all attempts). Record the time taken for the procedure and the movement score on the First Procedure Form.
25. Apply spray dressing/spot plaster.
26. Dispose safely of sharps and other waste.
27. If CSF obtained, measure serum/capillary glucose.
28. Dress infant and update parents.
29. Send samples to laboratory - the clearest sample from either attempt should go for microscopy. Usually:
 - a. Bottles 1 & 3 - Send to microbiology for microscopy, culture and sensitivity.
Microscopy on sample number 3
 - b. Bottles 2 & glucose sample - Send to biochemistry for glucose and protein
 Note: If best sample is blood only, please send sample to lab.
30. **If entering data directly onto OpenClinica:** complete the first or second procedure form.

GUIDANCE SHEET 4: LP Procedure

If using a paper log: use the First LP Procedure / Lab Results Log from the Participant Pack. If this is a second procedure, use a Second LP Procedure / Lab Results Log from the Document Box. File completed log(s) in the Participant Pack.

31. Place Participant Pack in the Active Participant File. If using a paper log, it will be entered onto OpenClinica by a delegated individual, once microscopy results are available.
32. Once all data has been entered onto OpenClinica, all paper logs can be filed in the participant's medical notes.

Number of attempts within a procedure and number of procedures

First procedure

If the first attempt fails (i.e. no CSF or frank blood obtained), a second attempt can be made during the same procedure by the **same operator** using the **same technique**. If the second attempt fails, the **procedure should be stopped**.

Second procedure and subsequent attempts

If deemed clinically necessary by the infant's Consultant, a **second procedure** should be attempted using the **same technique** by a **different operator** (ideally the next calendar day, but may be sooner if decided by the Consultant). Details of this **second procedure must be recorded in the Second Procedure Form on OpenClinica (Second LP Procedure / Lab Results Log may be used, and data entered onto OpenClinica at a later date)**.

If the second procedure fails after up to two attempts, the need for any further procedures and technique/personnel to be used will be determined by the infant's Consultant.

Please note: **at discharge, you will be asked to provide basic information on further procedures.**

GUIDANCE SHEET 4: LP Procedure

Post-Procedure

Parent communication

As soon as the LP procedure is complete, a member of the clinical team should speak to the infant's parents. They should explain whether the procedure was successful and what this may mean for the child (e.g. await results, need for a second LP procedure).

Parents should be asked to complete the second Parent Questionnaire, ideally within two hours of being informed of the microscopy results, or that the LP was unsuccessful if no CSF was obtained. The same parent who completed the initial Questionnaire should complete the second.

Once the second questionnaire is complete, ensure that the second questionnaire box on the front of the questionnaire is ticked, the parent's name and the study ID is completed. Then place the questionnaire in the Participant Pack. After completion, the questionnaire will be entered onto OpenClinica by a delegated individual. Once entered, all questionnaires should be sent to NPEU via nhs.net email (orh-tr.NeoCLEAR@nhs.net) or posted using pre-paid envelopes.

Laboratory results and immediate complications

Ideally, CSF samples should have microscopic examination within two hours.

Results will be recorded in the notes and acted on as per local unit policy. Please discuss the clinical plan with the infant's Consultant and inform the parents.

Results of the infant's LP microscopy and any immediate complications must be entered onto the electronic Procedure Form within OpenClinica.