Parent Information Leaflet

NeoCLEAR: Neonatal Champagne Lumbar punctures Every time – An RCT

NEO CLEAR
Optimising lumbar punctures in newborns

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Introduction

Many congratulations on the birth of your baby. We would like to tell you about a research study called NeoCLEAR. This research is for babies, like yours, who require a lumbar puncture. We'd like to tell you about this study so that you can decide whether or not you want your baby to take part. This information leaflet will explain why we are doing this study and what it would involve for you and your baby. Please take your time to read it through and discuss it with a member of the clinical team, or your friends and family if you wish. A member of the team caring for your baby, or one of the research nurses on this unit will be happy to answer any questions you may have.

What is the purpose of this study?

The aim of this study is to find out which technique is best to achieve a successful lumbar puncture. A lumbar puncture is a procedure which takes a small amount of fluid from the spine through a needle in the lower back. This fluid ('cerebrospinal fluid') is sent to a laboratory to help diagnose conditions such as meningitis.

Sometimes lumbar punctures do not result in a clear sample. Sometimes they have to be repeated. Currently, different doctors or advanced neonatal nurses use slightly different techniques. By finding out what the best technique is for this procedure, we could increase the number of successful lumbar punctures and reduce the need for repeat procedures. This could help with more accurate test results and diagnoses, reduce stress for the babies and their parents, and may help some babies to go home from hospital sooner.

We are looking at 2 different techniques to see if these impact the success of the lumbar puncture:

1. *Sitting* versus *lying down*

   The lumbar puncture would be carried out with your baby being held either in a sitting position or lying on their side.

2. *Early stylet removal* versus *late stylet removal*

   A stylet sits inside the needle to prevent skin cells getting stuck in the needle. During the procedure, the stylet would either be removed after the needle is through the skin but before it reaches the cerebrospinal fluid, or it will be removed from the needle after it reaches the cerebrospinal fluid.

Why am I being asked to take part?

Your doctors think that your baby requires a lumbar puncture. This is usually performed to help diagnose meningitis or another neurological condition, and sometimes as treatment for certain neurological problems.

What will happen if my baby takes part?

You will be asked to sign a consent form agreeing for you and your baby to participate in this research study.

Because no single technique is known to be better than another, the study will need to assign different babies to have lumbar punctures performed using slightly different techniques (all of which are currently used in hospitals). Using a computer program, the technique for each baby will be chosen at random, using one of the following lumbar puncture techniques:

a) *Sitting up* and *early stylet removal*
b) *Sitting up* and *late stylet removal*
c) *Lying down* and *early stylet removal*
d) *Lying down* and *late stylet removal*

The staff undertaking the procedure will know which option your baby has been allocated to, but this information would not normally be shared with you as the parents. This is to try to ensure that further decisions about their care are not affected by which technique they were assigned to.

We are also interested in how the results of a lumbar puncture affect parents. We will therefore ask you to complete a short emotions questionnaire before and after your baby's lumbar puncture.

Your baby will have their lumbar puncture performed by the clinical team. All practitioners involved in the study have received additional training in neonatal lumbar puncture, including all of the techniques above. If the first lumbar puncture does not work, the clinical team will use the same technique for the second procedure.

The Research Nurse or Doctor will collect some information about your baby from their hospital records up until your baby is discharged home.

What if I don't want my baby to take part?

You and your baby will continue to receive the standard care provided by this hospital, and this will not be affected in any way by your decision not to take part in research. For all lumbar punctures outside the study, the health professional will choose any of the above techniques, or other variations.

What if I change my mind?

You can withdraw yourself or your baby from the study at any time without providing a reason. Your baby will return to the usual care pathway and your decision will not affect the quality of care you or your baby receives.

What are the possible benefits to my baby taking part?

At present, we do not know which of the above techniques is best, we are hoping that the results of this study will help inform the care of babies in the future.

What are the possible disadvantages and risks of taking part?

All of the techniques used in the study are already used routinely within the NHS. At present, we don't know if one technique is better than the others, so your baby could be given any of them.

Will our information be kept confidential?

Yes. Your baby's data will only be accessed for the duration of the study. Your baby's information will not be identifiable when the results of the study are published in a medical journal. Data from this study may be shared with other researchers who are doing similar work, but your personal information will not be shared.

If you take part in the study, some personal information included in the consent form, such as your name, will be sent to the Co-ordinating Centre in Oxford where it will be held securely. Data collected during the study may be looked at by individuals from the University of Oxford (as the Sponsor), from regulatory authorities, the Co-ordinating Centre or the host Trust where this is relevant to this study.

What if new information becomes available during the study?

If new information becomes available during the study, the Trial Steering Committee will review it to see if any changes should be made to the study. Your hospital will contact you with any relevant information that affects your baby's care.

What will happen to the study results?

At the end of the study, the results will be published in a medical journal. You will be able to find information about this on our website: www. npeu.ox.ac.uk

Who is funding and organising this research?

The study is funded by the National Institute of Health Research (NIHR) Health Technology Assessment (HTA) programme (ref: 15/188/106).

The Co-ordinating Centre is the National Perinatal Epidemiology Unit Clinical Trials Unit (NPEU CTU) and the Sponsor is the University of Oxford.

Who has reviewed this research?

This research study has been reviewed and given approval by XXXXX Research Ethics Committee (ref: XXXXX).

What if there's a problem?

If at any stage you have concerns about this study or the way it has been carried out, you should talk to the doctor or nurse who is leading the study in this hospital. Their contact details can be found in the Contact Information section at the end of this leaflet.

If you remain unhappy and wish to complain formally, you can

do this through the NHS Complaints Procedure. Details of this procedure can be obtained from the following website http://www.nhs.uk/choiceintheNHS/Rightsandpledges/complaints/Pages/NHScomplaints.aspx. The contact telephone number for the Patient Advice Liaison Service (PALS) at this hospital is provided in the Contact Information section of this leaflet. PALS is unable to provide specific information about this research study.

Alternatively you may contact the University of Oxford Clinical Trials and Research Governance (CTRG) office on 01865 572224 or the head of CTRG, email ctrg@admin.ox.ac.uk.

In the unlikely event that your baby is harmed during the research, you may have grounds for legal action to obtain compensation against the University of Oxford as Sponsors of the study, but you may have to pay your legal costs. The NHS Complaints Procedure (mentioned above) will still be available to you.

Contact Information:

Should you have any questions or want to talk anything through, you can contact your local research team:

XXXX

The doctor leading this study at your hospital

XXXX

Patient Advice and Liaison Service (PALS)

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