Parent Information Leaflet

NeoCLEAR: Neonatal Champagne Lumbar punctures Every time – An RCT

NEO CLEAR
Optimising lumbar punctures in newborns

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Introduction

Congratulations on the birth of your baby. We would like to tell you about a research study called NeoCLEAR. This research is for newborn babies, like yours, who need a lumbar puncture. We would like to tell you about this study so that you can decide if you would like your baby to take part. This information leaflet will explain why we are doing this study and what it would mean for you and your baby. Please take your time to read it 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 method 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. At the moment, different doctors or advanced neonatal nurses use slightly different methods. By finding out what the best method is for this procedure, we could increase the number of successful lumbar punctures. This could reduce the need for repeat procedures and help with more accurate test results and diagnoses. This may reduce stress for the babies and their parents.

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

1. *Sitting* versus *lying down*

   The lumbar puncture would be carried out with your baby held either sitting up 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 needs a lumbar puncture. This is usually done to help diagnose meningitis or another brain-related condition, and sometimes as treatment for certain medical problems.

What will happen if my baby takes part?

You will be asked to sign a consent form. By signing this form, you agree to your baby taking part in this research study.

Of all the methods currently used, no single method is known to be better than any other. The study will assign different babies to have lumbar punctures carried out using slightly different methods (all of which are safely used in hospitals). A computer programme will choose the method for each baby at random. The chosen method will be one of the following:

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*

Your baby will have their lumbar puncture performed by the clinical team. All Nurses and Doctors involved in the study have received extra training in lumbar puncture in newborn

babies, including all of the methods above. If the first lumbar puncture does not work, the clinical team will decide if a second procedure is needed. If appropriate, the clinical team will use the same randomised method for the second procedure.

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

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

You and your baby will continue to get the standard care provided by this hospital. This is not affected in any way by your choice not to take part in research. For all lumbar punctures outside the study, the Nurse or Doctor will choose any of the above methods, or other variations.

What if I change my mind?

You can change your mind and remove your baby from the study at any time, without giving a reason. Your baby will return to the usual care pathway and your choice 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 methods is best. We hope 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 methods used in the study are used routinely within UK hospitals. At the moment, we don't know if one method is better than the others, so your baby could be given any of them.

We understand that this is a very stressful time for you and your baby. If you become distressed while taking part in this study, please speak with the doctor or nurse caring for your baby or you can talk with the local research nurse, whose contact details are at the end of this leaflet.

Will our information be kept confidential?

Yes. Your baby's personal data will only be accessed while the study is happening. Your baby will not be identifiable from the results of the study when they are published in a medical journal. Data from this study may be shared with other researchers who are doing similar work, but 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 Study Co-ordinating Centre in Oxford. It will be held there 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.

The Study Co-ordinating Centre will keep identifiable information about you from this study for at least 25 years after the study has finished. This is so that we are able to contact you in case a very long term effect of the lumbar puncture method is found. This is very unlikely.

For more information on how we process and protect your data, please see our website: www.npeu.ox.ac.uk/trials/privacynotice

What if new information becomes available during the study?

If new information becomes available during the study, a committee (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/neoclear

We will not be able to contact you directly to tell you the results of the study.

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 South Central - Hampshire B Research Ethics Committee Research Ethics Committee (ref: 18/SC/0222).

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 can talk with the doctor or nurse who is responsible for the study in this hospital. Their contact details are at the end of this leaflet.

If you are still unhappy and wish to complain formally, you can do this through the NHS Complaints Procedure. Details of this procedure can be found on the following website http://www.nhs.uk/choiceintheNHS/Rightsandpledges/complaints/Pages/NHScomplaints.aspx. The telephone number for the

Patient Advice Liaison Service (PALS) at this hospital is at the end 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 study, you may have grounds for legal action to obtain compensation against the University of Oxford as Sponsors of the study. Note: You may have to pay your legal costs. The NHS Complaints Procedure (mentioned above) will still be available to you.

Contact Information:

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

{_RESEARCHER_}

{_RESEARCHER_DETAILS_}

The doctor leading this study at your hospital

{_LEAD_}

Patient Advice and Liaison Service (PALS)

{_PALS_}

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Bliss for babies born premature or sick

Bliss offers support to parents and families of babies born premature or sick.

Call the Bliss helpline for information and support: 0808 801 0322

Open: Monday - Friday: 10am - 12noon, and Monday - Wednesday 7pm - 9pm

Or email hello@bliss.org.uk at any time and we'll get back to you within 3 - 5 working days

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