Parent Information Leaflet

Thank you for taking the time to read about this research study. We would like to invite you and your baby to take part in the SurfON study. This leaflet explains why we are doing this study and what it means for you and your baby. We know this is a stressful time for you and your family. Please feel free to discuss this with your family. We are happy to answer any questions.

What is the purpose of the study?

This study is about babies born two to six weeks before their due date. Babies born even a few weeks early are not fully developed. These babies may have breathing problems after birth, which can be severe. Some need to go onto a breathing machine (ventilator) soon after birth; others do not, but still need some help with breathing. They often go onto 'non-invasive' breathing support, which means that machines give oxygen through soft, short tubes in the nose or small masks over the nose.

The lungs of healthy full term babies naturally produce surfactant. This is a substance made up of proteins and fats that helps to keep the tiny air sacs in the lungs open, making it easier for them to breathe. Babies born early often do not make enough natural surfactant, or their surfactant does not work properly. As a result, babies may have difficulty expanding their lungs to take in oxygen. We can give a natural, animal-derived surfactant medication into the lungs, using a small tube put into the windpipe through the mouth. We do this routinely soon after birth in many babies born more than 10 weeks early to help their breathing.

At the moment, there have been no research studies into the timing of giving surfactant in babies born closer to term with breathing problems, so we have no guidance on this. Whilst some doctors prefer to use surfactant early, others do not, so clinical practice varies widely across hospitals in the UK. For this reason, we would like to know if it is better to give surfactant early, when a baby first starts to have problems, or see if they will improve without it.

Why are we being invited to take part?

Your baby was born between two and six weeks early and needs help with breathing.

Do we have to take part?

No, it is entirely up to you. If you decide not to take part, this will not affect your care or your baby's care. If you take part and then change your mind, you are free to withdraw at any time, although data collected up until withdrawal will be used in the study. You can withdraw by speaking to your baby's doctor. You do not have to give a reason.

What will happen if we take part?

We will ask you to sign a consent form. Your baby will be put into one of two groups, which will be decided by a computer program at random. There will be an equal chance of your baby being in either group. Babies in one group will receive a single dose of surfactant when they first start to need help breathing. In the other group the doctor will see if their breathing improves with non-invasive support alone. Regardless of which group your baby is in, they may still receive surfactant, if the doctor feels it becomes necessary.

We will collect some information about you and your baby such as length of stay in hospital, duration of non-invasive support and breast milk feeding from medical records. We will ask you to fill in a short questionnaire after you give consent and just before your baby leaves the hospital. We will also collect information through NHS digital or an equivalent national database, relating to survival and any hospital visits your baby has in their first year.

What are the possible disadvantages and risks from taking part?

Surfactant is routinely used in babies and there are no extra risks involved from taking part in the study.

What are the benefits from taking part?

Whilst there may not be any direct benefit in taking part in the study, your participation will be invaluable to help improve future care for these babies.

What will happen to the information collected about us during the study?

All information that we collect about you and your baby during the study will be kept strictly confidential and stored securely. You and your baby will not be identifiable in any publications of the results or reports from this study.

If you decide to take part, we will collect some personal information about you and your baby, including name, address and contact details. This information will be sent to the Study Coordinating Centre at the University of Oxford, National Perinatal Epidemiology Unit Clinical Trials Unit (NPEU CTU). Authorised members of the research team will hold this data and store it securely. Authorised staff from the University of Oxford (as Coordinating Centre) and University of Leicester (as Sponsor), funder, regulatory bodies, and your hospital may be given access to data for monitoring and/or audit of the study to ensure the research is complying with applicable regulations. Personal identifiable information including name, address, date of birth, gender and healthcare number will be shared with NHS digital or an equivalent national database.

The Study Coordinating Centre in Oxford will keep identifiable information about you and your baby from this study for 25 years after the study has finished.

Only anonymised information from this study may be shared with other researchers doing similar research in the future. None of your personal identifiable information will be shared with other researchers.

For more information on how we process and protect you and your baby's data, please see our website: **https://npeu.ox.ac.uk/ctu/privacy-notice**

Further information can also be found at the NHS Health Research Authority's website:

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Who is organising and funding the study?

The study is funded by the National Institute of Health Research (NIHR) [Health Technology Assessment (HTA) programme (Project reference 17/89/07)].

The study is sponsored by the University of Leicester, and will be run by the National Perinatal Epidemiology Unit Clinical Trials Unit (NPEU CTU) at the University of Oxford.

All research in the NHS is looked at by an independent group of people, called a Research Ethics Committee, to protect your interests. This trial has been reviewed and given favourable opinion by East Midlands - Derby Research Ethics Committee.

Further information:

We will send you a copy of the results at the end of the study and we will also share them on our website. If at any time you have concerns about this study, please speak with the doctors looking after your baby or contact the Sponsor at *rgosponsor@leicester.ac.uk*. In the event that something does go wrong and you are harmed during the research and this is due to someone's negligence then you may have grounds for a legal action for compensation against the Sponsor but you may have to pay your legal costs. The normal National Health Service complaints mechanisms will still be available to you (if appropriate).

If you would like to contact an independent organisation, we suggest that you contact Bliss, a special care baby charity.

Bliss
for babies born premature or sick

https://www.bliss.org.uk
020 7378 1122
hello@bliss.org.uk

The Patient Advice and Liaison Service (PALS) is a confidential NHS service that can provide you with support that you may have regarding the care you receive as an NHS patient.

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NPEU Clinical Trials Unit

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SurfON

Surfactant Or Not

For babies born early with breathing problems

Multicentre, open-label, randomised controlled trial of early surfactant therapy versus expectant management in late preterm and early term infants with respiratory distress.