

Important things to know about BESS:

- One of the hospitals near you is taking part in a study called BESS: The Bronchiolitis Endotracheal Surfactant Study.
- You have been given this information sheet as you might be asked later about your baby taking part in BESS.
- Your baby has Bronchiolitis, a winter viral chest infection.
- Some babies with Bronchiolitis need intensive care where they can be given help with their breathing from a Mechanical Ventilator.
- We want to know if a liquid called surfactant can help babies get off the Mechanical Ventilator sooner.
- If your baby does need intensive care, one of the doctors or nurses in the intensive care unit might ask you about taking part in BESS. You'll be given some more information and can ask any questions you might have.
- Taking part is voluntary and if you don't want your baby to take part then you don't need to give a reason why. Deciding not to take part will not affect the standard of care for your baby.

Contact Details

If you would like to speak to anyone about this study please contact your local BESS team on:

0161 701 8056

You can also learn more about BESS on our website:

www.bess-trial.org.uk

The views expressed in this publication are those of the authors and not necessarily those of the MRC, NHS, NIHR or the Department of Health and Social Care.



BESS Study Information Sheet

V2.0 18/09/2018

IRAS ID: 220853



Information Leaflet

Why have I been given this leaflet?

We are sorry that your baby is ill. You have been given this leaflet because your baby has bronchiolitis, a chest infection, and may need intensive care to help with their breathing.

If your baby is transferred to a Paediatric Intensive Care Unit (PICU) that is taking part in BESS, you might be asked about taking part. This leaflet is to give you some information about BESS before you arrive at the PICU.

The doctors and nurses in PICU will give you some more information about the study and you'll be able to ask any questions that you might have. Your baby will only take part in BESS if you choose to, and if you agree we will ask you to sign a consent form.

The priority of PICU staff will be your baby and their care, and if you choose not to take part in BESS this will not affect the standard of care your baby receives.

Bronchiolitis

Bronchiolitis is a winter viral chest infection that causes breathing difficulties in babies. There is no vaccine and no specific treatment for Bronchiolitis.

Sometimes babies with bronchiolitis need intensive care where they can be given help with their breathing from a Mechanical Ventilator.

Why are we doing the BESS study?

We are doing the BESS study because we want to know whether a liquid called surfactant could help babies with bronchiolitis to reduce the time they need to be on the Mechanical Ventilator.

The results from BESS will help doctors and nurses treating babies with Bronchiolitis to know whether or not they should use surfactant in the future.

Surfactant

Surfactant is a liquid made in healthy lungs that helps the lungs to inflate more easily. When a baby has bronchiolitis, their lungs don't make as much surfactant as they normally do. The surfactant we are using in BESS is called 'poractant alfa' also called it's brand name 'CUROSURF®'.

Surfactant has been used in premature babies with other lung problems for over 30 years, but we don't know if it will work in babies with bronchiolitis.

What happens in BESS?

If your baby takes part in BESS neither you nor your babies doctors or nurses will get to choose what treatment they get. We use a computer to decide "at random" whether your baby is given surfactant or just air. This is called "randomisation".

Your baby will be given surfactant or air up to a maximum of three times and we will collect some information about them while they are in hospital. This will help us to understand whether or not surfactant helps babies breathe on their own more quickly.

Do you and your baby have to take part?

No, you do not have to take part. However, before you make your final decision we would suggest that you find out more about the study by speaking to one of the BESS team in the PICU. You could also look at the BESS website (contact and website details can be found at the back of this leaflet), or speak to your baby's doctors and nurses.

Who is involved in the study?

This project is funded by the Efficacy and Mechanism Evaluation (EME)* programme a Medical Research Council (MRC) and National Institute for Health Research (NIHR) partnership. It has been organised by The University of Liverpool and approved by an independent Research Ethics Committee and National Health Research Authorities. **The EME Programme is funded by the MRC and NIHR, with contributions from the CSO in Scotland and Health and Care Research Wales and the HSC R&D Division, Public Health Agency in Northern Ireland.*