BESS
Bronchiolitis Endotracheal Surfactant Study

NHS

<Trust/Site address 1>
<Trust/Site address 2>
<Trust/Site address 3>
<postcode>
Tel: <telephone number>

Parent/Person with Parental Responsibility Information Sheet

Contents

Contacts for further information

If you would like more information or have any questions about the BESS, please talk to:

Principal Investigator: **<PI NAME>**

Research Nurse: **<RN NAME>**

Telephone: **<number>**

Or visit the website: www.bess-trial.org.uk

Thank you for taking the time to read this information sheet. We hope you will find this information helpful.

You and your baby are invited to take part in BESS. Here are some important things to know:

- BESS is a study running across the UK, looking at treatment of babies with Bronchiolitis. BESS is organised by the University of Liverpool.
- You have been given this information sheet as your baby might be eligible to take part in this study.
- 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.
- At present there is no specific treatment for Bronchiolitis.
- We want to know if a liquid called surfactant can help babies get off the Mechanical Ventilator sooner.
- We will give half the babies in BESS surfactant, and half the babies air as a 'dummy' (placebo).
- Before you decide whether or not to take part, it is important for you to understand why the research is being done and what it will involve for your baby and you. Please read the following information carefully and discuss it with friends or relatives if you wish.
- Taking part is voluntary. 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.
- Please ask a member of your clinical team if there is anything that is not clear, or if you would like more information.

Why are we doing the BESS study?

Bronchiolitis is a winter viral chest infection that causes breathing difficulties in babies. There is no vaccine and no specific treatment for Bronchiolitis. Babies with Bronchiolitis may need intensive care where they can be given help with their breathing from a Mechanical Ventilator.

BESS is a study looking at whether a liquid called surfactant could help babies with Bronchiolitis to reduce the time they need to be on the Mechanical Ventilator. 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.

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 known by the brand name 'CUROSURF®'. CUROSURF® has a European Marketing Authorisation and is licensed in the UK for use in babies with some breathing conditions, but not currently Bronchiolitis.

We would like 284 babies age 6 months and under to take part in BESS. If your baby was born prematurely and has a corrected age of under 6 months, then they can still take part in BESS.

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.

Why have we been asked to take part?

We are inviting your baby and you to take part in this study because your baby is a patient at one of the hospitals taking part in the BESS study, and has been diagnosed with Bronchiolitis.

What will we have to do if my baby takes part?

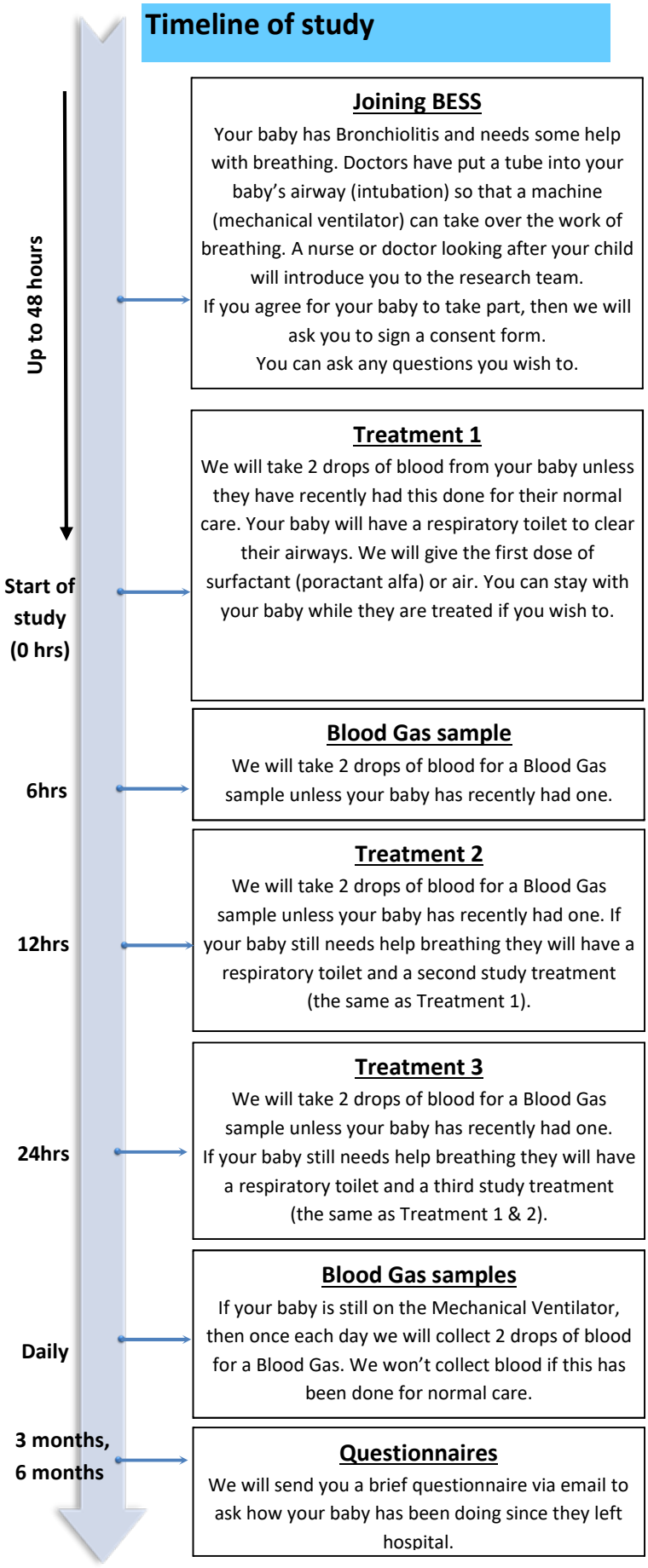
A member of the clinical team will be available to talk to you about BESS and you will be able to ask any questions that you have. If you have had all of your questions answered and are happy for your baby to take part, then you will be asked to sign a consent form. You will be given a copy of the consent form and this information sheet to keep.

If you agree to your baby taking part in BESS, they will be given surfactant or air (the dummy or 'placebo') up to three times over 24 hours. If your baby gets better quickly they might only need to be given the study treatment one or two times.

A Respiratory Physiotherapist is a specialist who helps look after babies and children with breathing problems. Before giving surfactant or air, a Respiratory Physiotherapist or other suitably qualified member of staff will suck out any thick secretions (mucus) in your baby's upper airway and breathing tube, by flushing with a very small amount of safe salty water (saline). This is called respiratory toilet or tracheal toilet. This helps stop sticky mucus in your baby's airway from causing a blockage. Performing a respiratory toilet does not hurt your baby and is part of normal care. Babies with Bronchiolitis are likely to have several respiratory toilets even if they don't take part in BESS, because this disease causes thick sticky secretions in the airways and these need to be removed to help your baby to breathe.

Babies on PICU have very small blood samples taken each day to check how much breathing support they need from the Mechanical Ventilator. We call these "Blood Gas" samples because we use them to look at the amount of oxygen and other gases in their blood. These samples are about 2 drops of blood and are usually taken from a "line" or a heel prick.

Timeline of study



What will we have to do if my baby takes part? Continued.

We need to know the Blood Gas results before and after we give each study treatment to understand if the treatment is working. If your baby takes part in BESS, then they will have 3 more Blood Gas samples in the first two days of the study than they would if they didn't take part. To avoid disturbing your baby, we won't do a Blood Gas if your baby has recently had one done as part of their usual care. These "Blood Gas" samples will not be stored for research and will be discarded after use. This would be the same whether your baby takes part in BESS or not.

We will collect information about your baby's time and treatment in hospital to understand whether or not the surfactant helps babies with Bronchiolitis to breathe on their own and recover more quickly.

We will send you a questionnaire by email at 3 months and 6 months after your baby takes part in BESS. If the study is extended we may also send you a questionnaire at 12 months after your baby takes part in BESS, but you will not receive more than 3 questionnaires in total. At 3 months we will only ask whether your baby has been back to hospital since they took part in BESS. At 6 and 12 months we will ask you to answer some questions about how your baby has been getting on with their breathing. If you do not have an email address, we can send you a paper copy. These questionnaires take around 10 minutes each to complete. With your permission, we will run a computer check using your baby's NHS/CHI/Health & Social Care number [delete as appropriate to site] to make sure you are contacted only when it is appropriate.

What are the alternatives for treatment?

If you do not agree to your baby taking part in BESS, they will receive standard care for Bronchiolitis. Your baby will stay on the Mechanical Ventilator for as long as they need help with their breathing. However, at present there is no specific or alternative treatment for Bronchiolitis.

Does my baby have to take part?

No, you can decide that your baby should not take part in this research. If do you decide now that your baby will take part, you can also change your mind in the future and decide that they should stop taking part.

Either way, the standard of care your baby receives now or in the future will be the same whatever you decide.

What is surfactant and where does it come from?

Surfactant is a liquid containing fats and proteins made in healthy lungs that helps the lungs to inflate easily. The surfactant we are using in BESS is called 'poractant alfa'. It is extracted and purified from pig lungs (a 'porcine derivative' medicine). Many medicines come from animals. Religious authorities have long established views on the use of such medicines. The following religious authorities have reviewed BESS and given their opinion on this study:

For Muslim parents: The Research & Documentation Committee of The Muslim Council of Great Britain have advised that there is provision under Sharia Law for Muslims to use porcine derivatives in severe and life-threatening situations.

For Jewish parents: The Kashrus & Medicine Information Service of the United Synagogue and the Union of Orthodox Hebrew Congregations have confirmed that as surfactant avoids the mouth and is delivered directly into the lungs through a breathing tube, it is deemed acceptable (*halochoh*). Furthermore, Jewish dietary laws are suspended where life is threatened, so there is mitigation were some surfactant to find its way into the mouth. Also, there is scope for leniency as the surfactant has been chemically treated by the purification and extraction processes meaning it is no longer animal flesh.

How will I know which treatment my baby is going to have?

You and the hospital team caring for your baby will not know which treatment your baby is given. In research studies we often split patients up into groups to look at how different treatments work.

In the BESS study there are two treatment groups:

- One group will receive surfactant (poractant alfa).
- The other group will receive air as a placebo (a 'dummy' procedure)

It is really important that each group in the BESS study has a similar mix of patients in it. This is so we know that if one group of patients does better than the other it is very likely to be because of the treatment, and not because there are differences in the types of patients in each group.

We use a computer programme that puts patients 'at random' into one of the groups – you might hear this described as 'randomisation' or 'random allocation', but they all mean the same thing. In the BESS study your baby is equally as likely to be in the group receiving surfactant as they are in the group receiving air.

Neither you nor your doctor can choose which group your baby will be in. You and the doctors and nurses looking after your baby won't know which group your baby is in, but if there is a problem your baby's doctors and nurses will be able to find out which group your baby is in.

What are the benefits and risks of taking part?

Surfactant has been used in preterm babies for over 30 years and is a safe treatment for breathing problems caused by prematurity. There is some information suggesting that surfactant might help babies with Bronchiolitis, but not enough evidence to give doctors confidence that it should be used routinely. Some doctors do use surfactant when treating babies in intensive care with Bronchiolitis, but others don't. We don't know how well surfactant works in these babies, which is why we are doing this study.

If your baby receives surfactant, a potential benefit of this treatment might be a reduced period of time spent on the Mechanical Ventilator, which could reduce the risk of

complications associated with being on the Mechanical Ventilator and in intensive care.

Before surfactant or air is given, your baby will have a respiratory toilet to reduce the risk of thick secretions blocking the tube into your baby's lungs. Even with the respiratory toilet, there are some temporary side effects that often occur in the first few minutes after surfactant is given, such as: a slowed heart rate ('bradycardia'), low blood pressure ('hypotension'), or a drop in blood oxygen level ('desaturation'). These problems are commonly seen in babies in intensive care with Bronchiolitis who are not given surfactant just because they are so unwell. The hospital team caring for your baby will look out for these problems and will make sure your baby gets extra support if needed.

The results from the study will help doctors and nurses in the future decide whether they should or should not treat babies with Bronchiolitis with surfactant.

What happens if I change my mind?

If at any point you decide to stop taking part in the study your baby will receive the treatment and follow up usually offered by your hospital. If you decide that you no longer want your baby to take part, we will ask you if you would like to:

- continue to complete follow-up questionnaires for the study and provide data or
- stop taking part with no more study questionnaires or data collection and

We will use any study information collected up until the time you stop your baby taking part. This information will be stored separately from your name or other identifiers, so you cannot be identified by the people looking at the study information.

If you decide to stop taking part in the study, the study team may still need to collect some limited information about your baby and any side effects they may have as a result of taking part in the study. This will only be collected if required by the Regulatory Authorities.

Will our participation be kept confidential?

Yes. All information collected about your baby and you during the course of the study will be handled according to all applicable ethical and legal requirements.

All personal information will be kept strictly confidential and will only be accessed by people working on the study or working to ensure the study is being run correctly.

Your baby's healthcare records may be looked at by authorised individuals from their hospital, the Study Team, the University of Liverpool (the study Sponsor) or the regulatory authorities to check that the study is being carried out correctly.

Your baby will be allocated a study number, which will be used to identify them on each paper form. Your full name, your email address, your telephone number (if you agree), your baby's full name and their date of birth will be included on your consent form and a copy of this will be sent to the coordinating centre for the study (the Liverpool Clinical Trials Centre at the University of Liverpool (LCTC). Every effort will be made to ensure that any further information about you that leaves the hospital will have your name removed so that you cannot be recognised from it. This information will usually be removed by a member of the study team at your hospital but may also be removed by the LCTC upon receipt.

With your consent, we will send a letter to your baby's GP to let them know your baby is taking part in this study.

Your baby's NHS hospital will collect information from their medical records for this research study in accordance with the University of Liverpool instructions.

Your baby's NHS hospital will use your name and contact details to contact you about the research study, and make sure that relevant information about the study is recorded for their care, and to oversee the quality of the study. Individuals from The University of Liverpool, the Liverpool Clinical Trials Centre (LCTC, part of the University of Liverpool) and regulatory organisations may look at your baby's medical and research records to check the accuracy of the research study. Your baby's NHS hospital will pass these details to the University of Liverpool along with the information collected from your baby's medical records. The only people in the University of Liverpool who will have access to information that identifies you or your child will be people who need to contact you to send you the study questionnaires, send you updates about the study if you have agreed to this, or audit the data collection process. The people who analyse the information will not be able to identify your baby and will not be able to find out yours or their name or contact details.

Your baby's NHS hospital will keep identifiable information about your baby's involvement in BESS for 25 years after the study has finished.

What will happen to the results of the study?

It is intended that the results of the study will be presented at conferences and published in medical journals so that we can explain to the medical community what our research results have shown. Confidentiality will be ensured at all times and you will not be identified in any publication. If you agree to being contacted by us, we will invite you to a meeting for parents at the end of the study to hear about the results.

What if there is a problem?

If you have a concern about any aspect of this study, you should ask to speak with one of your hospital's research team who will do their best to answer your questions (contact details on page one of this information sheet).

If you remain unhappy and wish to complain formally, you can do this through the NHS Complaints Procedure. Details can be obtained from your hospital.

The University of Liverpool holds insurance cover for this trial on a legal liability basis. This excludes claims relating to clinical or medical negligence.

If you or your baby are harmed by taking part in this research study, there are no special compensation arrangements. If you or your baby are harmed, and this is due to someone's negligence, then you may have grounds for a legal action for compensation against the NHS Trust where you are being treated but you may have to pay for your legal costs. The normal National Health Service complaints procedures should be available to you.

*Additional information

This study is funded by the Efficacy and Mechanism Evaluation (EME) Programme, an MRC (Medical Research Council) and NIHR (National Institute for Health Research) partnership.

The study has been reviewed for scientific content by the National Institute for Health Research EME Programme Board.

The Health Research Authority and National Research Ethics Service have reviewed the study and given approval for it to take place. This study was reviewed by the South Central Berkshire Research Ethics Committee.

The University of Liverpool is responsible for managing this study. They have asked that the day to day running of the study is carried out by the Liverpool Clinical Trials Centre (LCTC), part of the University of Liverpool. The Study Investigators, the LCTC and the Parent Experience team at the University of Liverpool, the University of Southampton and the University College London are the Study Team.

The University of Liverpool is the sponsor for this study based in the United Kingdom. We will be using information from your baby's medical records in order to undertake this study and the University of Liverpool will act as the data controller for this study. This means that we are responsible for looking after your and your baby's information and using it properly. The University of Liverpool will keep identifiable information about you and your baby for 25 years after the study has finished.

Your and your baby's rights to access, change or move your information are limited, as we need to manage your information in specific ways in order for the research to be reliable and accurate. If your baby is withdrawn from the study, we will keep the information about you and them that we have already obtained. To safeguard your and their rights, we will use the minimum personally-identifiable information possible.

You can find out more about how we use your information at **www.bess-trial.org.uk**.

If you wish to discuss the study with someone independent of the research team you can contact the local NHS Patient Advice and Liaison Service (PALS) or equivalent on: <telephone number>

Thank you for reading this information sheet.

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.

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

<Trust/Site address 1>
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Tel: <telephone number>

Parent/Person with Parental Responsibility Consent Form

To be completed by the Researcher:

Site Name:	
Participant Study Number	-
Participant NHS/CHI/H&SC number	
Participant Initials:	Participant DOB: / /

To be completed by the parent/person with parental responsibility:

Once you have read and understood each statement please enter your initials in each box	**Initial**
Example: I confirm that I have read and understood the information sheet.	EX
1. I have read and understood the information sheet for this study. I have had the opportunity to ask questions and have had these answered satisfactorily.	
2. I understand that participation is voluntary and that I am free to withdraw my baby from the study at any time, without giving a reason, and without my baby's care or legal rights being affected. I understand that in some cases further information about any unwanted effects of my baby's treatment may need to be collected by the study team.	
3. I understand that our data will be retained for a maximum of 25 years at site and at the Liverpool Clinical Trials Centre (LCTC) part of the University of Liverpool and that they will be stored in a confidential manner.	
4. I give permission for a copy of my consent form which will include my name and email address and my baby's name, date of birth, postcode and NHS number to be sent to the LCTC (where it will be kept in a secure location), to allow confirmation that my consent was given.	
5. I understand that I will be sent no more than three questionnaires via email, and give permission to be contacted in this way. I have provided my email address below.	
6. I give permission for my baby's NHS/CHI/Health & Social Care [delete as appropriate to site] number to be sent to Alder Hey Children's Hospital NHS Foundation Trust to ensure that I am only contacted when it is appropriate.	
7. I understand that relevant sections of my baby's medical notes and any data collected during the study may be looked at by authorised individuals from the Study Team and those listed under *additional information, NHS Trust and Regulatory Authorities. I give permission for these individuals to have access to my records.	
8. I agree to allow information or results arising from this study to be used in future healthcare and/or medical research in an anonymised form.	
9. I agree to my GP being informed of my baby's participation in the study.	
10. I agree to my baby taking part in the above study.	

<Trust/Site address 1>
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Parent/Person with Parental Responsibility Consent Form

To be completed by the Researcher:

Site Name:	
Participant Study Number	-
Participant NHS/CHI/H&SC number	
Participant Initials:	Participant DOB: / /

The following are optional – your baby can still take part in BESS even if you don't agree to these:

11. I would like to receive BESS newsletters (no more than two per year) and the results of the study when available.
(If you agree to this statement please provide your details below) ☐

12. I agree that I may be contacted in the future in relation to this or other related studies.
(if you agree to this statement provide your details below) ☐

To be completed by the parent/person with parental responsibility:

Please provide your email address in order to receive no more than 3 brief study questionnaires, and newsletters if you have agreed to this.

Contact details:	
Email address:	

Your baby's **full** name (please print):		
Your signature:		Date:
Your **full** name (please print):		

To be completed by the Researcher, after the parent has signed:

Researcher **full** name (please print):		
Researcher signature:		Date:

Once both the parent and researcher have completed the consent form, three copies should be taken; the original should be filed in the Investigator Site File, 1 x copy in the participant medical notes, 1 x copy given to the parent(s) and 1 x copy returned to the LCTC.