Participant Information Sheet
The SABRE trial of hypertonic saline in acute bronchiolitis

Why is this research study being done?
Acute bronchiolitis is a common, distressing illness affecting children. A virus infects the lungs, and then the airways become blocked, leading to difficulties with breathing. It is the most common reason why children are admitted to hospital, with 1–3% of all children admitted to hospital during their first winter. The majority of those admitted with the condition are under six months of age and the associated stress for parents is considerable. After forty years of research the best treatment we have is supportive care and oxygen.

Recent research suggests that salt water, sprayed as a mist so that the children can breathe it in ('nebulised 3% hypertonic saline') might help children with acute bronchiolitis. Scientists think that the salt water changes the mucus which blocks the airways so that it can be cleared more easily. Three small research studies suggested that a child's time in hospital could be reduced by up to a quarter by using this treatment. If this was true, it would be good for children, their families and the children's wards trying to cope with the large numbers admitted with bronchiolitis every year. However these studies were small and undertaken in countries with very different health care systems. There have been a number of other treatments that people have suggested might be useful on the basis of small studies but in all cases this proved not to be the case when larger UK studies looked at the question in more detail. This study will help us determine whether this apparently simple treatment should be adopted in the treatment of young children with acute bronchiolitis.

Why am I being asked to take part?
The nursing and medical staff at this hospital have diagnosed your child with acute bronchiolitis. This is one of eight hospitals taking part in a new research study. We would like to include your child in the study.

Do I have to take part?
No. It is up to you to decide whether or not to take part. If you do, you will be given this information sheet to keep and be asked to sign a consent form. You are still free to withdraw at any time and without giving a reason. A decision to withdraw at any time, or a decision not to take part, will not affect the standard of care you receive.

What will happen if I take part?
All babies admitted to hospital with acute bronchiolitis will receive usual care which involves providing oxygen therapy, if required, and fluids through a feeding tube if they are struggling to feed normally.

If you agree to take part in the study and sign the consent form, your child will be "randomly allocated" to receive either: a) nebulised hypertonic saline in addition to usual care or b) will continue with usual care. The randomisation will be performed by a computer and cannot be influenced by the doctors or nurses. The nebuliser is used every six hours in those who will be receiving this treatment, and the nebuliser treatment will be started as soon as the child is included in the study. There will not be any other changes in the care of children in either group from the normal care of children with acute bronchiolitis.

During your child's stay we will record information regarding their progress every 6 hours. This will include whether they need oxygen therapy and help with feeding. The time taken for them to be fit to go home will be recorded. After your child goes home we will ask you to keep a diary of how they are each day for the next four weeks and to complete a questionnaire at the end of four weeks which will give an indication of the effect of the illness on your child and your family to help to find out whether the treatment has a useful effect.

What do I have to do?
If you would like your child to take part in the study, you will be asked to sign a consent form. Researchers and staff may then collect information from your child's medical records for the research. When your child leaves hospital you will be given a diary to complete about your child's symptoms over the next month, and also a questionnaire to complete and post back. A Research Nurse will telephone you over the next month to help you to complete the diary and questionnaire.

Are there any side effects to the treatment?
The nebuliser is a small soft facemask that will be held over your child's mouth and nose. It turns the salt water [saline] into a fine mist that can be breathed in. The use of the nebuliser may cause your child to cry and breathing in the saline may make them cough. Previous research studies using hypertonic saline have found no evidence that this is harmful to children and it is being used routinely in some hospitals. Although several hundred babies with acute bronchiolitis have been treated with hypertonic saline without problems it is possible some unexpected harmful effects may occur.

In the event that something does go wrong and your child is harmed during the research study there are no special compensation arrangements. If your child is harmed and this is due to someone's negligence then you may have grounds for a legal action for compensation against the University of Sheffield or XXX Hospital but you may have to pay your legal costs. The normal National Health Service complaints mechanisms will still be available to you.

What are the possible benefits of taking part?
We cannot promise that the study will help you or your child but doing the study may help to improve the treatment of other children with acute bronchiolitis in the future.

What will happen to information recorded about my child?
We will inform your GP that you have taken part in this study. A member of the research team will record information about your child's treatment whilst he/she is in hospital from your hospital notes and computer records and during the month after being in hospital. The information you send back to us on the symptom diary and questionnaire will be recorded on a computer.

All information that is collected about you during the study will be kept strictly confidential. The information will be stored in a secure area of the hospital and on a protected computer file, both of which can only be accessed by the research team and regulatory authorities. We will destroy all identifiable information five years after the end of the study. An anonymised copy of the computer file (with any details that might identify you or your child removed) will be kept and made available to other researchers for use in future studies.

What if there is a problem?
If you have a concern about any aspect of this study, you should ask to speak with the researchers who will do their best to answer your questions (contact details below). If you remain unhappy and wish to complain formally, you can do this through the NHS Complaints Procedure. Details can be obtained from the hospital.

What will happen if I don't want to carry on with the study?
You can withdraw from the study at any time. We will need to keep the information you have given up to the time you withdraw but will not collect any new information.

Who is organising and funding the research?
The research is organised by the University of Sheffield and funded by the Department of Health.

What will happen to the results of the study?
We will publish the results in a scientific journal and produce a report that is freely available to anyone who wishes to read it. You or your child will not be personally identified in any report or publication we produce. Please contact us using the details below if you would like to see a summary of the results when the trial is completed, in about two years time.

Who has reviewed the study?
This study was given a favourable ethical opinion for conduct in the NHS by the Yorkshire and the Humber - South Yorkshire Research Ethics Committee.

Who can I contact if I need more information?
Kirsty Sprange, Trial Manager Clinical Trials Research Unit, ScHARR, University of Sheffield Regent Court, 30 Regent Street, Sheffield, S1 4DA. Tel: 0114 2222969. Email: k.sprange@sheffield.ac.uk
Study website: www.shef.ac.uk/scharr/sabre

Please keep this information sheet