University of Southampton

School of Medicine
Primary Medical Care

Primary Medical Care
University of Southampton
Aldermoor Health Centre
Aldermoor Close
Southampton SO16 5ST
United Kingdom

Tel +44 02380 241050
Fax +44 02380 701125
Email pmc1@soton.ac.uk

A double-blind randomized placebo-controlled trial of topical intranasal steroids in 4- to 11-year-old children with otitis media with effusion (OME) in primary care

Patient Information Sheet

Invitation

Your child is being invited to help with a research study looking at 'glue ear' or 'otitis media with effusion' (which is its medical name) and whether a steroid nasal spray is a good treatment for it. Before you decide, it is important for you to understand why the research is being done and what it will involve. Please take time to read the following information carefully and feel free to discuss it with your GP or the research nurse at the practice. You can also obtain further information about the study by contacting us at the address given at the end of this information sheet.

What is the purpose of the study?

'Glue ear' is a very common condition in children and is particularly common over the winter months. It is a type of catarrh or 'glue' behind the eardrum, which can cause the child to lose some hearing and lead to a variety of different problems. Many children affected by this condition will recover on their own, however some children also have recurrent or persisitent catarrh in their ears and may need further medical treatment and referral. This study aims to see whether a steroid nasal spray given over three months can help such children.

Why has my child been chosen?

Your practice has noted from their records that your child has already had one or more ear infections or ear related problems over the last year that may be associated with glue ear. They are therefore inviting you to an appointment with the practice research nurse for a test that can detect if your child currently has any 'glue' behind the eardrum. This is a simple painless five minute test.

Does my child have to take part?

No. It is completely up to you to decide whether your child takes part or not. If you do decide to take part you are still free to withdraw at any time and you do not have to give a reason. If you do decide not to take part or to withdraw your child from the study this will not affect the standard of care you or your child receive from the practice.

What will happen to my child if they take part in the study?

If you agree that your child can take part, then you and your child will be asked to come into the practice for an appointment with the research nurse to have an ear test. The ear test can detect any 'glue' behind the eardrum. If your child is found to have 'glue' behind both their ears then this will be deemed sufficient for them to be eligible to enter the main part of the study.

If you decide to let your child participate in the next part of the study, your child will be allocated at random to either a steroid nasal spray or a nasal spray without medication (called a 'placebo'). This is like tossing a coin to decide which group your child is in. You will not know which spray your child takes, nor will the doctors and nurses in the research team. This is because sometimes if patients and the research team know what medication is being given in a research study it may affect the results.

Your child will take the nasal spray for three months and the practice research nurse will show you how to give it. It is sprayed once a day in each nostril. In the first week of your child starting the spray the practice research nurse will telephone you to make sure that you are not having any problems. Whichever group your child is in they will continue to receive your practice's recommended management for glue ear.

After your child has been taking the spray for a month we will conduct some more ear tests. During the time your child is taking the spray we will ask you to keep a simple diary, filled in once a week for convenience, about the child's symptoms and how they are. We ask you to do this for a total of three months in two diaries. At the end of the three months that your child has been taking the spray for we will again conduct some ear tests. Your child's final visit will be six months after they have finished the nasal spray and again we will conduct some more ear tests. At each visit we will ask you to complete some questionnaires about your child and their health and we will also measure and weigh them. Every time you visit we will also ask you to bring in the bottle of steroid spray so we can check there are no problems with it. The practice nurse will also check your child's notes over two years for consultations related to their ear problems.

What are the possible risks of my child taking part?

The steroid spray has been extensively tested and we are not expecting any side effects. The spray does, however, very occasionally produce short lived nosebleeds, stinging in the nose and discomfort, and more rarely heavier nosebleeds. If there are any side effects that we had not foreseen we would be able to quickly find out what spray your child had been allocated to. Also, as an additional check, we will be monitoring your child's height and weight every time they visit as there is an extremely slight risk of height being affected.

Medical indemnity arrangements

If your child is harmed by taking part in this research project then they are covered by the University of Southampton's indemnity insurance. If you are harmed as a result of general clinical management, for example due to someone's negligence, then you are covered by the GP's own indemnity insurance. Regardless of this, if you do wish to complain about any aspect of the way you have been approached or treated during the course of this study, the normal NHS complaints mechanisms will be available to you.

Will my child taking part in this study be kept confidential?

Yes. A study number will be used instead of your child's name and address. This means that the data collected will be kept anonymous. All information will be treated in accordance with the Data Protection Act.

What will happen to the results of the research study?

It is anticipated that the results of the study will be published a year after the conclusion of the research. No child will be identified by name in any publication. The study spray is not currently available for this condition outside of this clinical study nor is it possible to give a repeat prescription whilst in the study.

Who is organising the funding of the research?

The NHS Health Technology Assessment Programme is sponsoring this study. Unfortunately we are unable to reimburse you for your travel expenses.

Contact for further information

The Study Manager, Dr Sarah Benge, Department of Primary Care, University of Southampton, Aldermoor Health Centre, Aldermoor Close, Southampton SO16 5ST. Telephone 023 000 0000.

What if I have any other concerns?

If you have any problems, concerns or other questions about this study, you should contact The Study Manager, Dr Sarah Benge, at the above address or discuss them with the research nurse at the practice.

The Metropolitan MREC, one of 13 national research ethics committees, has given its approval for this study.

THANK YOU FOR READING THIS DOCUMENT AND FOR ANY HELP YOU DECIDE TO GIVE

IF YOU DO CHOOSE TO LET YOUR CHILD TAKE PART IN THE STUDY PLEASE KEEP THIS INFORMATION SHEET

YOU AND YOUR CHILD ARE FREE TO WITHDRAW FROM THE STUDY AT ANY TIME

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Patient Information Sheet for (6- to 11-year-olds)

You may have got glue ear, which is something a lot of children have.

This means that you could have sticky fluid in your ear that can stop you hearing quiet noises.

Your doctor is helping us with a study to find out better ways of treating glue ear.

If you like you can help us to do this by joining our study.

If you want to join us here's what will happen.

You will have your ears tested by the nurse, then if you have glue ear you will be asked to use a spray in your nose and help the grown-ups keep a diary of how you feel.

If you have any questions ask the nurse and they will try to answer them.

YOU ARE FREE TO WITHDRAW FROM THE STUDY AT ANY TIME

*This information sheet is to be given to the patient if aged between **6 and 11 years of age** in addition to the parents receiving the more detailed patient information sheet.*