

Autoinflation Randomised Study in school age children (4-11 years) with glue ear (AIRS).

Parent 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 technique called autoinflation 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 persistent catarrh in their ears and may need further medical treatment and possibly referral. This study aims to see whether auto-inflation can help improve the health and quality of life of such children.

Why has my child been chosen?

Your practice has noted from their records that, 1) Your child is at an age where glue ear is quite common and is just about to start or has recently started school this year, or 2) They have already had one or more ear infections or ear related problems over the last year that may be associated with glue ear noted in your child’s health records. 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. We have shown in other studies that even seemingly healthy children aged 4-6 years old often get glue ear in the winter and spring terms (about 1 in 4 children on average per term and sometimes higher).

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 accurately detect any “glue” behind the eardrum. If your child is found to have “glue” behind one or both of their ears then this will be deemed sufficient to confirm a degree of impaired hearing for them to be considered eligible to enter 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 the autoinflation method of treatment and usual care or they will receive usual care only from their GP (e.g. a decongestant, information or watchful waiting). Being allocated at random is like tossing a coin to decide

which group your child is in. We are doing this because we do not yet know if autoinflation is an effective treatment but several studies suggest it is.

Your child will continue with their initial assigned treatment (for one month after which they will come to see the research nurse again for another ear test. If your child's ear(s) are better they will not continue with any treatment, **however** if their ear (or at least one of their ears) is not better your child will be asked to continue treatment (autoinflation and usual care or just usual care) for a further two months. We ask all study children to come back and see the research nurse at the end of the treatment/usual care period for a final check to see if all is clear at three months. Study children that were not in the autoinflation group and still have glue ear after a test three months (the more persistent or troublesome cases) will be offered autoinflation at that point to use if they want. Study children that received autoinflation for three months and still have glue ear at the three month test will be asked to see their GP.

During the time your child is taking part in the study we will ask you to keep a simple diary, filled in once a week for convenience, about your child's symptoms and how they are. You will be asked to do this for the first month and the second two months (three months in total). At each visit we will ask you to complete some questionnaires about your child and their health. The practice nurse will also check your child's notes at six months after they entered the study, looking for ear related consultations over that time.

What will my child have to do?

Your child will have to have their ears tested at the beginning of the study. Your child may or may not be then suitable to go further into the study, this depends on whether or not they have glue ear in at least one ear, and whether you and your child are happy to be randomised into the study.

If your child is in the autoinflation treatment group you and your child will be shown how to use the balloon by the nurse. Your child will have to use this 3 times a day every day for one month in the first instance and then if not cured for a further two months.

All children will receive usual care and they will receive the standard treatment provided by your practice for your child's condition such as a decongestant, information, watchful waiting or referral. Your child will need to carry out whatever usual care instructions given by your GP/practice for three months.

All children in the study will be asked to have three ear tests, one will be at the beginning of the study, the second will be one month later and the third will be a total of three months from starting the study.

Some children will be asked to repeat the screening test straight after using the balloon to see if we can predict who will get better fastest.

What is autoinflation?

This is a technique in which a child blows up a special balloon using their nose rather than their mouth. The purpose is to open the Eustachian tube (the tube that connects the middle ear to the throat) and allow pressure in the middle ear to return to normal. Continued use of autoinflation over several weeks has been shown to help some children with glue ear get better faster. Autoinflation is a 'low-tech' way of helping some children, with no known harms. It can be made into a game, but it needs adult supervision and it may require quite a little practice at first so it is important to persevere.

What are the benefits of my child taking part?

Your child's usual care will not be affected in any way. Benefits include accurate monitoring of progress and offering autoinflation, a new treatment suggested to help by the National Institute for Health and Clinical Excellence (NICE). The small studies done so far look promising, suggesting auto-inflation may indeed be an effective treatment, particularly when children are school aged and prepared and able to use the treatment regularly. This approach may avoid more serious glue ear developing and subsequent referral and grommets in some children. The research is being done to clarify if and how effective this new treatment is. We do know it is very safe indeed from all the studies done so far.

What are the possible risks/side effects of my child taking part?

There have been no reported side effects of using this balloon so far. It does produce a pressure change in the nose comparable to swimming under water at a depth of about 2 feet. The idea that this blows germs into the ear from the back of the nose seems unlikely, especially since the previous British small study showed that ear infections were in fact more common when the balloon was not used than when it was. Most people accept that “blowing the nose” is good hygiene for both children and adults. We will however monitor any potential side effects such as an increase in respiratory infections.

Using the nose to blow up a balloon can be uncomfortable, especially the first few times this is done. The nurse will advise how to stretch the balloon to minimise any discomfort

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.

What happens when the research study stops?

The autoinflation treatment is available over the counter, so when the study has ended you and your child will be able to carry on using it should you wish to purchase it or alternatively your GP could prescribe it if they thought it was suitable for your child’s condition before the results of this study were published.

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.

Who is organising the funding of the research?

The University of Southampton is the sponsor of this study and the NIHR Health Technology Assessment Programme is the funder. Unfortunately we are unable to reimburse you for your travel expenses.

Contact for further information

The Study Manager, *name to be inserted*, Primary Care and Population Sciences Division, University of Southampton, Aldermoor Health Centre, Aldermoor Close, Southampton SO16 5ST. Telephone *number to be inserted*

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, *name to be inserted* at the above address or discuss them with the research nurse or GP at your practice.

All research in the NHS is looked at by an independent group of people called a Research Ethics Committee to protect you and your child’s safety, rights, wellbeing and dignity. This study has been reviewed and given favourable opinion by the Southampton and South West Hampshire Research Ethics Committee.

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 AND YOU WILL ALSO GET A COPY OF YOUR SIGNED CONSENT FORM

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

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Patient Information Sheet for 6-11 year olds

What is research? Why is this study being done?

Research is an important way we try to find out the answers to questions using science - a way of discovering things. We want to see if blowing up a balloon (like in the picture) treats poorly ears better than what is usually used.



What autoinflation means is blowing up a balloon using your nose just like in this picture!

Why have I been asked to take part?

It is possible you may have sticky ears which are something a lot of children get. Doctors and adults call it glue ear. This means that hearing quiet noises like whispers or what people are saying can be hard sometimes, especially when there is a lot of noise being made by other people. Your doctor is helping us with a study to find out better ways of treating sticky-glue ear.

Who has checked the study is ok and safe to do?

Before any research is allowed to happen, it has to be checked by a group of people called a Research Ethics Committee. They make sure that the research is fair. Your study has been checked by the *to be inserted* Research Ethics Committee.

Do I have to take part?

No you don't have to take part in this study and even if you do take part you can leave at any time, it's up to you.

What will happen to me if I decide to take part in the study?

If you want to join in here's what will happen. First you will have your ears tested by the nurse, then if you have sticky ear you may be asked to use either the balloon three times a day, or we may just keep an eye on you for a while to check it goes away. You and your parents will keep a diary of how you feel. You will see the nurse 3 times and she is able to see you after school or in the holidays so you don't need to miss any school.

Primary Medical Care

University of Southampton, Aldermoor Health Centre, Aldermoor Close, Southampton SO16 5ST, United Kingdom

Tel: [REDACTED] Fax: [REDACTED]

Will blowing up the balloon with my nose upset me?

No, it will just feel a little bit like blowing your nose when you blow up the balloon. For the first few times blowing up the balloon can be uncomfortable. No children have been hurt doing this and you can stop blowing whenever you want. Once the balloon has been blown up a few times it gets much easier to do just like when you blow up balloons with your mouth.

Might anything else about the study upset me?

We don't think there will be anything about joining in that will upset you, but if you do become upset by something please let your parents know and they can phone the nurse or you can tell the nurse when you see her again.

Will joining in help me?

We cannot promise the study will definitely help you. The information we get should help treat children with sticky ears in better ways in the future. You will get a chance to have a go with the balloons if you have got sticky ears, either straight away or later. So far it looks good that these balloons do help make it go away.

What happens when the study stops?

At the end of the study you will have helped us to see if the balloon is a good way of helping children with sticky-glue ear. It may take us a while to work this out but during that time if you wanted to still use the balloon you could ask your doctor to give it to you on a prescription or your grown ups could buy it from a chemist shop. So if you find it helped you, you can keep using it for longer.

What if something goes wrong ?

We do not think that anything will go wrong during the study but if it did we (your doctor, nurse and the University of Southampton) would make sure no harm comes to you and we would make sure everything was put right.

What if a better medicine or treatment comes along?

If this happens it will not matter that you are helping us with this study, you will get the treatment that is best for you.

What if I don't want to do the study anymore?

If at any time you don't want to do the study anymore, just tell your parents, doctor or nurse. They will not be cross with you. Your doctor will help you decide which medicine or treatment is best to use afterwards.

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

*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.*

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Patient Information Sheet for 4 and 5 year olds

To be shown/read to the child by their parent/guardian

It can sometimes get a little sticky inside children's ears. This may make it hard for some children to hear whispers and people speaking - especially when there is a lot of noise being made all around.



Your doctor is helping us to find out ways of getting children with sticky ears better as quick as we can

If you like you can help us by joining in.

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

You can see what will happen in the picture.

You will have your ears tested by the nurse. It will not hurt, but you will hear a buzzing noise and might feel a tiny "pop"

Afterwards you may then be asked to blow up a special balloon three times a day using your nose to see if it makes the ear better.

You can see this in the picture.

Blowing up the balloon like this can be a little tricky at first. But it gets much easier to do after you have practised it a few times. It soon gets more comfortable and can be fun to do - seeing how big you can get the balloon!



Your mummy or daddy will ask you how you are feeling and how your ears are while you get them better again. If you have any questions about helping us please ask the nurse and they will answer them for you.

YOU CAN STOP WHENEVER YOU LIKE

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