

# What is OSTRICH all about?

The study is called **OSTRICH: Oral Steroids for the Resolution of otitis media with effusion in Children.**

Otitis media, also known as glue ear, is a common condition, especially in young children. Whilst we know that glue ear usually gets better by itself, in thousands of children each year it can cause hearing loss, which can lead to further problems such as difficulty with learning and speech development. If hearing loss lasts longer than 3 months, children are often offered hearing aids or a grommet operation.

Some research studies have found that taking a prescribed steroid medication (these steroids are commonly used to treat asthma and other conditions and are not the same as steroids that are used to build muscles) for a short period seems to result in glue ear getting better in some children. However, the studies that have been done so far have been small, have mostly not measured the effect on hearing, and have not measured how long any effects last.

If treatment with an oral steroid does improve hearing then it is likely that some children can avoid needing an operation or having to wear a hearing aid.

This study aims to provide a more definite answer to these questions. We plan on recruiting 380 children aged between 2 to 8 years who have glue ear for at least 3 months.

## For this study we will...

If you are happy to go ahead, your child will be assigned at random to receive one of two treatments for one week. The two treatments are: an oral steroid or an oral placebo\*. You will be asked to

*\*A placebo is a substance that appears to be identical to the medication but that has no medical effects in the body.*

dissolve the required number of tablets in **water**, and give to your child to drink once a day at breakfast time for 7 days.



## If we decide to take part, what will happen to my child?

- Your child will have a hearing assessment (this is part of the normal care that your child will receive whether they take part in the study or not, and may occur on the day of your clinic visit or on another day).
- When you and your child attend the Ear, Nose and Throat (ENT) clinic/ Paediatric Audiology & AVM clinic, your child's Clinician will assess whether your child has glue ear and discuss treatment options with you.
- If your child's Clinician thinks that your child is eligible for OSTRICH study then they will discuss the study with you. If you are interested in the study and nobody mentions it to you, please feel free to ask a member of the clinic staff.
- A member of the OSTRICH team will check that your child is suitable and that you are happy for them to take part, and ask you to sign a Consent Form.
- You will be given the study treatment for your child to take at home.
- You will have further appointments at the clinic for hearing assessments.

## How long will this take?

Taking part in the study means spending approximately 30 minutes with the research nurse at your clinic appointment who will ask about your child's symptoms. You will be given a simple diary to fill in at home (daily for one week and then weekly for the next four weeks) to let us know how your child has been.



## Would there be any follow-up?

You and your child will be asked to attend a follow up appointment for your child to have another hearing assessment. There will also be a brief questionnaire to fill in. These follow up appointment will be at the end of 5 weeks, 6 months and 12 months.

## What are the possible disadvantages and risks of taking part?

Taking part in the study will mean that we ask you to give up some of your time. There is a chance that your child might develop side effects from the study treatment, but the steroids used in this study are the same type of steroids GPs prescribe every day for conditions such as asthma, and the risk of side effects is very small.

## What are the possible benefits of taking part?

If the steroid treatment works there is a chance that your child's hearing will improve faster than normal, and this may mean that they no longer need grommet surgery or hearing aids. In addition, you will be helping us answer questions about the treatment of glue ear in children that should result in better care for children with glue ear in the future.

## Do we have to take part?

No. Your child does not have to take part in this study. Participation in the study is entirely voluntary and you and your child are free to refuse to take part or withdraw from the study at any time without having to give a reason. If you decide not to take part or to withdraw from the study, this will not affect the care that your child receives.

## What will happen if we don't want to carry on with the study?

You can decide for your child to stop taking part at any time by phoning the Study Manager on 029 2068 7609. In order for us to understand the reasons why parents withdraw their children from the study, we may ask you why you have decided to withdraw. However, you do not have to give any reasons.

## What will happen to the results of the research study?

At the end of the study the results will be published in medical journals and presented at medical conferences. This will allow us to tell other doctors and healthcare professionals about the results of the study. Information that identifies you or your child will not be presented. We will provide you with information of where to access the published study.

We will also update you with newsletters regarding the study during and at the end of the study.



### Chief Investigators:

#### Dr Nicholas Francis

Reader Institute of Primary Care & Public Health  
Cardiff University, School of Medicine  
Neuadd Meirionnydd,  
Heath Park, Cardiff, CF14 4YS

#### Professor Christopher Butler

Professor of Primary Care Medicine  
Institute of Primary Care and Public Health  
School of Medicine, Cardiff University  
Neuadd Meirionnydd  
Heath Park  
Cardiff, CF14 4YS

#### OSTRICH Study Manager

Tel: 029 2068 7609

email: [OSTRICH@cardiff.ac.uk](mailto:OSTRICH@cardiff.ac.uk)

Website: [www.ostrich-study.co.uk](http://www.ostrich-study.co.uk)

***If you are interested in taking part in the study please read the Parent Information Sheet. If have any questions, please ask to speak to a member of the OSTRICH team.***



# Introducing The OSTRICH Study

**Oral Steroids for the Resolution of  
otitis media with effusion in  
Children Study**

Steroid treatment



Placebo treatment



Your child will have an equal chance  
of getting one of two treatments.



**For more information please ask to  
speak to a member of the OSTRICH  
team!**

