OSTRICH

Oral **ST**eroids for the **R**esolution of otitis media with effusion **I**n **CH**ildren Study

Information Sheet for Parents & Guardians

South East Wales Trials Unit
Uned Ymchwil De-ddwyrain Cymru
sewtu
Cardiff University
Prifysgol Caerdydd
<insert site logo>
GIG NHS Wales
Byrddau Iechyd Health Board
NHS
National Institute for Health Research

We are inviting you and your child to take part in this research study run by Cardiff University.

Before you decide if you want your child to take part, we would like you to understand why the research is being done and what it would involve for you.

Please read this information sheet carefully.

One of our team can go through the information sheet with you and will answer any questions you have.

Should you have any further questions or require further information about your child taking part you can contact (during normal working hours):

OSTRICH Study Manager
South East Wales Trials Unit (SEWTU),
7th Floor, Neuadd Meirionnydd, Heath Park, Cardiff, CF14 4YS
Tel: +44 (0)29 20687609 E-mail: **OSTRICH@cardiff.ac.uk**

Please note that this number is only for queries regarding the study; if you have an urgent medical problem please contact your doctor in the normal way.

Alternatively, you can visit our study website on:

www.ostrich-study.co.uk

The Principal Investigator for this site is:-

Mr xxxxxxxx

Tel: xxx xxxxxxxxx

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WHAT IF THERE IS A PROBLEM?

If at any point you are unhappy with any aspect of the study, please advise the South East Wales Trials Unit (SEWTU) research team (contact numbers below), or your ENT Clinician. If you remain unhappy and wish to formally complain, you can do this through the normal NHS complaints procedure.

WHAT DO I NEED TO DO NOW?

If you agree to consider having your child take part in the study please tell your ENT Clinician whether or not you are happy for your child to take part. If your child is old enough you will probably want to discuss the study with them. The research nurse can help you discuss the study with your child.

Thank you for reading this information sheet and considering participation of your child in this study**.** Our team is experienced, and dedicated to doing this important study to the highest international standards, and helping to improve the future care of children with glue ear.

WHY DO WE WANT TO DO THE STUDY?

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

Several small research studies have suggested that treatment with oral steroids (cortisone or corticosteroids) might help glue ear get better quicker. These oral steroids reduce inflammation in the body and are often used to treat conditions like asthma (these steroids are not the same as steroids that are used to build muscles). However, the research done so far is not as good as we would like it to be, so we still can't say for definite **whether a child with glue ear will benefit (improved hearing, glue ear gets better, no longer needs an operation for grommets) from treatment with an oral steroid.**

We want to answer these questions by testing the use of oral steroids (*Prednisolone sodium phosphate*) in a research study. We are looking to recruit 380 children aged between 2 to 8 years.

WHY HAS MY CHILD BEEN ASKED TO TAKE PART?

Your child's Clinician thinks that your child may have glue ear, and has identified that they could be eligible for the **OSTRICH** study.

DOES MY CHILD HAVE TO TAKE PART?

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 do decide not to take part or to withdraw from the study, this will not affect the care that your child receives.

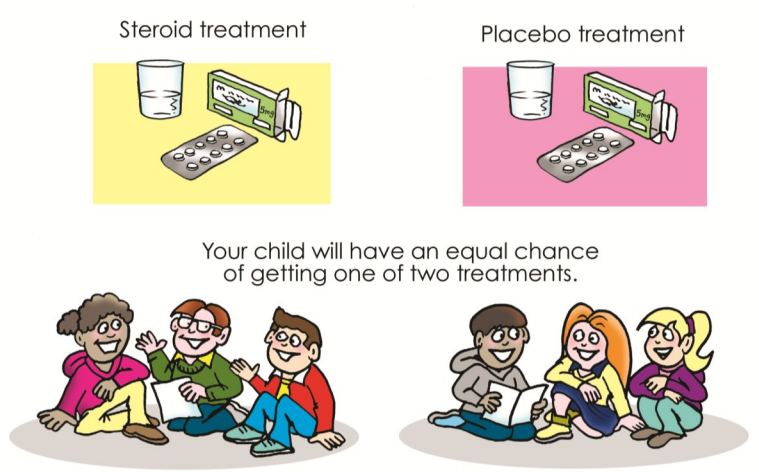
WHAT IS THE STUDY TREATMENT?

The treatment your child receives will either be an oral steroid *(Prednisolone sodium phosphate) or* a matched placebo[1]. Both the steroid and placebo are identical and have exactly the same engravings on them.

The study treatment is a soluble tablet dissolved in water and given in a drink.

In order to make sure that beliefs about a treatment do not influence the results of the study, we will not tell you nor your ENT Clinician which treatment your child is receiving (although any Clinician that is treating your child can find out at any time if they need to). At the end of the study we will be able to tell you which treatment your child received if you would like to know.

Please see the diagram below:



[1]A placebo is a substance that appears to be identical to the treatment but that has no medical effects in the body.

WHAT IF I, OR MY CHILD, DO NOT WANT TO CARRY ON BEING PART OF THE STUDY?

You can decide for your child to stop taking part in the study at any time and without needing to give a reason. If you wish, you can contact the study manager or let the research nurse know next time they contact you. 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.

If you decide to stop taking part, your child's medical care and the legal rights of either you or your child will not be affected in any way.

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 during, and at the end of the study.

WHO HAS FUNDED AND APPROVED THE STUDY?

This study has been funded by the National Institute for Health Research Health Technology Assessment (NIHR HTA) Programme and is being managed by Cardiff University.

The study has been approved by the NHS Research Ethics Committee (REC) for Wales (reference: 13/WA/0004). The committee makes sure that the study is conducted ethically and in accordance with the requirements of the Clinical Trials Regulations. Their job is to protect your safety, rights, wellbeing and dignity.

OSTRICH

Side effects are uncommon with these treatments (especially when only taken for short periods of time), and are not usually serious. Possible side effects can include nausea (feeling sick), vomiting (being sick), indigestion (upset stomach) and changes in behaviour or mood.

Side effects are more likely to occur if you take a long course of steroids (more than 2-3 months), or if you take short courses repeatedly.

If your child experiences any problems with the treatment you should contact your GP and the study manager (details at the end of this sheet).

It is advised that your child is not given any immunisations whilst they are taking the study treatment and for 1 month after study participation.

Whether or not your child enters this study there is a chance that their glue ear may get better or worse.

WILL MY TAKING PART BE KEPT CONFIDENTIAL?

All information, including any personal information, collected about you and your child during the course of the study will be kept strictly confidential.

We follow ethical and legal practice. Your GP and ENT Clinician will know that you have agreed for your child to participate in the study. However, they will not see your answers to the questionnaires or your diary. Neither your name nor your child's name will be given out or appear on any publications.

We will store the information collected during this research study including your child's details for a minimum time of 15 years, though we may store for longer. This is because the regulations require storage until the youngest participant has reached 21 years if that has not already happened within the original 15 years. This information will be stored securely and confidentially by the research team at Cardiff University in accordance to the 1998 Data Protection Act and only the study team will have access to this information.

WHAT HAPPENS IF YOUR CHILD TAKES PART?

<u>At your first visit to the Ear, Nose and Throat (ENT) clinic:</u>

- You will see the ENT Clinician who will examine your child's ears and conduct a hearing test.
- A Clinician in the ENT clinic will talk to you about the study and assess whether your child is suitable to take part.
- If your child is suitable, and you are happy for them to take part, the Clinician will ask you to sign a consent form.
- If your child is old enough they will also be given information about the study. If they would like to take part, they will be given an assent form which asks them to write their name to confirm that they would like to take part.
- If you and your child are happy to go ahead, a member of the OSTRICH team will ask you some questions about your child's hearing and collect some basic clinical information (this should take between 10-30 minutes).
- Your Clinician will issue a prescription for the study treatment. The Hospital Pharmacist will provide this for you.
- Your Clinician will also discuss other treatment options with you. Your child can still be referred for hearing aids or be placed on the waiting list for grommet surgery, even if they are taking part in the study, if this is what is recommended by the ENT Clinician. If you wish your child to be placed on the waiting list for surgery then the ENT Clinician will discuss with you whether or not they still need to be on the waiting list when they are seen for an assessment at 5 weeks. If they do go on to have surgery then they will not have to wait longer because they have taken part in the study.
- You will be provided with a diary to complete at home over the next 5 weeks.

At home:

- You will be asked to dissolve the study treatment in water and give it to your child to drink once a day at breakfast time for 7 days. You may wish to have another drink ready to give to your child to take the taste away.

- Additional tablets will be contained in the box of medication that you will be supplied with and tablets will be left over at the end of the course. Your child must only take the required daily dose for seven days. You will be asked to return the unused medication and packaging at the 5 week follow up appointment.

- You will be asked to complete a short diary every day for the first week whilst your child takes the treatment, then once weekly for the next 4 weeks to record your child's symptoms and any additional treatments they have had. This should take 5-10 minutes to complete each time. The diary will also ask whether your child has attended the doctors or whether there has been a loss of school or work because of your child's symptoms.

At the second visit (Week 5):

- After 5 weeks your child will have another appointment .

- A member of the OSTRICH team will check how your child is doing, collect the diary and any unused study treatment from you, and ask you to complete a questionnaire (this should take less than 20 minutes in total).

- Your child will have a hearing assessment.

- If your child's hearing has substantially improved, and you had decided to have them listed on the waiting list for surgery, then removing them from the waiting list could be discussed at this time.

- Unused medication will be collected from you at this time.

Additional follow up visits (6 and 12 months):

- At 6 and 12 months after your child joined the study, you will be asked to attend an appointment . Your child's hearing will be assessed and you will be asked to complete a questionnaire.

- We will collect information about your child that is held and maintained by The Health and Social Care Information Centre and other central UK NHS bodies from their medical records and other health-related records. This information will be looked at by the research team during the trial but will be kept confidential.

WHAT ARE THE POSSIBLE ADVANTAGES ABOUT TAKING PART?

By participating in this study there may be a possibility that if the treatment works, your child's hearing will improve so that wearing hearing aids or having grommet surgery is not required. Your child will also have extra assessments which you might find helpful. 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 this condition in the future.

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.

Possible side effects

There is a chance that your child might develop side effects from the study treatment. However, the steroids used in this study are the same types of steroids that GPs prescribe every day to treat common conditions such as asthma, and the risk of side effects will be no greater than if they were prescribed for these other common conditions.