The Newcastle upon Tyne Hospitals NHS
NHS Foundation Trust

Royal Victoria Infirmary
Queen Victoria Road
Newcastle upon Tyne
NE1 4LP

Tel: 0191 233 6161
Fax: 0191 201 0155

A Feasibility Pilot Study for a Randomised Controlled Trial Comparing Surgery to Observation for Intermittent Exotropia [X(T)]

Information About The Research (v4 07.07.11)

We would like to invite you to take part in a research study. Before you decide you need to understand why the research is being done and what it would involve for you. Please take time to read the following information carefully. Talk to others about the study if you wish.

(Part 1 tells you the purpose of this study and what will happen to you if you take part. Part 2 gives you more detailed information about the conduct of the study).

Ask us if there is anything that is not clear or if you would like more information. Take time to decide whether or not you wish to take part.

Part 1

Why has my child been invited to take part?

Your child has been diagnosed as having a type of squint known as Intermittent Exotropia [X(T)]. This is the type of squint that this research project is designed to help us understand. We are aiming to recruit 100 children to take part in the trial.

Do we have to take part?

No. Taking part is entirely voluntary. You should read this information sheet and discuss it with the Ophthalmologist who is looking after your child. Once you have done that and asked any questions that you may have it us up to you to decide. You may also wish to discuss the study with friends and family or your GP. You can also talk it over with someone like the Patient Advisory Liaison Service (PALS) who are an independent body. Their contact details are at the end of this leaflet.

Not taking part will not affect the standard of care that your child receives. If you join the study and then change your mind you can withdraw at any point.

What is the purpose of the feasibility study?

There are several different ways to treat Intermittent Exotropia; glasses, patches, surgery but most often it is decided to do nothing, called active monitoring. One reason that many children receive no treatment is that there is uncertainty about which treatments are best for this type of squint. We plan to carry out a Randomised Controlled Trial (RCT) to compare surgery to active monitoring. Because conducting a trial requires a lot of time, money and commitment from everybody involved it is important that we get it right. Parents and/or doctors might have strong ideas about which treatment they feel is best so it might be difficult to recruit enough participants to carry out a full trial. To ensure that a full trial is feasible we are first going to do a 'Pilot Study'. We would like you to help us by agreeing to take part in the Pilot.

What is a Randomised Controlled Trial?

There are lots of different ways to carry out research studies. Some of them are better than others at providing answers that you can rely on. Randomised Controlled Trials are well recognised as being the gold standard way to test whether and how well a procedure or treatment works. In a randomised trial the participants are placed in to groups by chance (randomly). This is important to make sure the groups are as similar as possible at the start.

What will happen if I agree to my child taking part?

There is some evidence that some children who receive no treatment get better on their own. Surgery can improve control of the squint but any operation carries certain risks (see below). There is uncertainty regarding which children are helped by an operation and which can get better without any treatment. In situations like this where we don't know which way of treating patients is best we put people into groups and give each group a different treatment. The results are compared to see if one is better.

Your child will be placed in to one of two groups. One group will have an operation to straighten the eye. The other group will be asked to wait for nine months before an operation is considered. Which group your child is placed in will be decided by chance (randomly).

What will I have to do?

The follow up appointments that you will be asked to attend will depend on the group that you are placed in. The appointment schedules for the two groups can be seen below;

Active Monitoring Group:

Recruitment clinic
3 months monitoring clinic
6 months monitoring clinic
9 month outcome visit

Surgery Group:

Recruitment clinic
Operation within 3 months of recruitment
2 week post operative monitoring visit
3 month post operative monitoring visit
6 month post operative outcome visit

All appointments will take place at the hospital. At the first and last visits we will also ask you to complete a short questionnaire telling us about your child's general wellbeing.

What are the possible benefits/risks of taking part?

Active monitoring group
There is a small chance that if your child does not have an operation straightaway that the squint might get worse. Children in this group will be carefully monitored for signs of this happening. If it seems that the squint is getting worse you will be able to leave the group and have an operation straightaway.
It is also possible that during the six months the squint will improve and your child might not need an operation at all.

Surgery group
The risks involved in having an operation are the same whether you join the study or not. The doctor who is going to do the operation will discuss these with you and give you a chance to ask any questions that you might have.
The benefit of having the operation is that surgery can improve the control of the squint.

Will my taking part be kept confidential?
Yes. We will follow ethical and legal practice and all information about you will be handled in confidence. It is usual for a persons' GP to be informed that they are taking part in a trial and we will ask you for permission to write to your GP to tell them.

This completes Part 1. If the information in Part 1 has interested you and you are considering participating please read the additional information in Part 2 before making your decision.

Part 2

Who has reviewed the study?

All research in the NHS is looked at by an independent group of people called a Research Ethics Committee to protect your safety, rights and well being. This study has been reviewed and given a favourable opinion by Sunderland Research Ethics Committee.

Who is funding and organising the study?

Four hospitals are taking part in the Pilot study in Newcastle, York, Moorfields and Sunderland. Money for the project has been provided by the Health and Technology Assessment programme run by the National Institute for Health Research (NIHR). The NIHR is part of the NHS and is therefore government funded

What will happen to the results of the study?

The pilot study will tell us whether or not it is likely to be possible to recruit families to the study. If it appears to be feasible we will apply for the necessary funding and carry out a full scale trial.

Further information and contact details

General information about taking part in research can be found at www.invo.org.uk

If you want to talk over taking part in this study with someone impartial you could discuss it with your GP or the Patient Advisory Liaison service (PALS) at your hospital (contact details below).

North of Tyne PALS, Freepost RLTC-SGHH-EGXJ, The Old Stables, Greys Yard, Morpeth, NE61 1QD.
Tel. 0800 0320202,
e mail northoftynepals@nhct.nhs.uk

If you have a concern about any aspect of this study, you should ask to speak to the researchers who will do their best to answer your questions [Christine Powell on 0191 282 4040 or Mr. M Clarke on 0191 282 4002]. If you remain unhappy and wish to complain formally, you can do this by contacting either the PALS or the Patient Relations Department, Newcastle Upon Tyne Hospitals NHS Trust, Freeman Hospital, High Heaton, Newcastle upon Tyne NE7 7DN (tel: 0191 233 6161),