



Sam Exo

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

Information About the Research for Children 10 to 16 years (v2 07.07.2011)

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.

Why am I being asked to take part?

You have a type of squint known as Intermittent Exotropia. The doctors and your parents know that there is an operation that might make the squint happen less often. Doctors are not sure which children are helped by this operation. We would like you to help us find out.

Why is the research being done?

The operation is carried out on lots of children every day so we know that it is safe. We want to find out though what happens to your eyes if you don't have the operation. To do that we need some children to agree to wait a bit longer before they have the operation. Instead of having your operation soon you might be asked to wait 6 months.

How do I know that the research is a good idea and will be done well?

All research in the NHS is looked at by an independent group of people called a Research Ethics Committee. They make sure the study is safe. This study has been looked at by the Sunderland Research Ethics Committee and they have given us permission to do it.

What will happen if I agree to take part?

Sometimes we don't know which way of treating patients is best. To find out we need to put people in to different groups and give each group a different treatment. To make sure the two groups are the same each patient is put in to a group by chance (randomly). If you take part a computer will decide whether you have your operation soon or if you are asked to wait.

Do I have to take part?

No. It is up to you to decide. You can talk it over with your parents and the doctors or you might know someone else who you trust to help you make your mind up. If you decide you do want to take part we will ask you to sign your name below.