



Patient Information Leaflet for Children & Adolescents

7 -15 Years Old

A study about children with arm injuries

Hello. We would like to ask you and your family if you would take part in an important study called the SCIENCE Study.

WHAT IS THE SCIENCE STUDY?

The SCIENCE Study is finding out the best way to treat an injury like yours. Your arm has an injury to a bone in the elbow. A piece of bone has broken off, and this is called an 'epicondyle fracture'. About one thousand children have this injury each year in the UK. Doctors can treat these injuries in two different ways. They can rest the elbow in a cast or splint and allow it to heal naturally, or can do surgery to fix the bone. The doctors at this hospital are taking part in the study, because we are uncertain about the best way to treat these injuries.

WHY ARE YOU ASKING ME?

You are being asked to take part because your doctor believes that either treatment would be suitable for you. We are asking lots of children in the country who have the same injury as you if they will think about taking part in the SCIENCE Study.

WHAT TREATMENT WILL I GET?

The treatments are:

- Resting the arm in plaster cast for up to 4 weeks, to allow it to heal by itself.
- Surgery to fix the bone, usually with a screw and then resting the arm in a splint or cast for up to 4 weeks.

There are good points, and bad points about each treatment, which are discussed in detail online at www.SCIENCEstudy.org.

The way we compare the treatments fairly is to split the children into two groups who are the same, by a process called randomisation. You can't choose the treatment, and neither can the doctors, it is done by a computer. When we have groups of patients who are as similar as possible, we can then compare them in the best possible way.

DO I HAVE TO SAY YES?

No you don't. If you decide to say no, nobody will mind and you, your parents, doctors and nurses can talk about what treatment you will have.

WHAT WILL HAPPEN IF I SAY YES?

One of your doctors or nurses will ask you to sign a form called an "Assent Form". This is just to say that you understand the study and what will happen. You will be given a copy of the form to keep, as well as this information leaflet.

Your parent or guardian will need to sign a consent form to agree to you taking part as well.

We will then learn which treatment group you have been put in, by the process of randomisation. Doctors and nurses can then begin your treatment.

We will ask you to answer some questions about how much you can use your arm. We'll send these questions four times over the next year, and then yearly until you are fully grown at 16 years old. These will be sent to the mobile phone or e-mail address that your family tells us to.

WHO WILL KNOW I'M IN THIS STUDY?

You will be given a special identification number and any information that you give us will be linked only to this number. This means that only the people who are treating you, or who need to contact you, will know who you really are.

WHAT HAPPENS IF I CHANGE MY MIND?

You can change your mind at any time and we will stop contacting you. If you do change your mind please ask your parents to let your doctor or one of the research team members know.

If you have any questions or worries about the information in this leaflet or anything else related to the study please speak to one of your nurses or doctors. Further details of the study can be found in the parent version of the information leaflet given to your parent/guardian, and available online at www.SCIENCEstudy.org/info

Thank you for reading this leaflet

SCIENCE Study

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