

A study about children with arm injuries

Patient Information Sheet and Assent Form (For patients 12-15 years old)

Study title: **SCIENCE**

Sponsor: University of Oxford, UK (Starship Child Health in NZ)

Locality: Auckland District Health Board Ethics committee ref.: 21/NTB/161
Starship Child Health

NZ Chief investigator: Dr Nichola Wilson Contact phone number: 0211441162

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. 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. It is important that you talk to your parents/whānau and the doctors/nurses before you make a decision to take part in the study. If you do not want to take part in the study, you may still need treatment including surgery or a cast.

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. 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

Thank you for reading this leaflet

Assent Form

12 to 15 years olds

Study title (lay): **SCIENCE**

Locality: Auckland District Health Board Ethics committee ref.: 21/NTB/161
Starship Child Health

Lead investigator: Dr Nichola Wilson Contact phone number: 0211441162

Does the child wish to complete an assent form? **Yes/No**

PLEASE select your answer to the questions below (Yes or No)

- | | YES | NO |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------|--------------------------|
| • Has somebody explained the study to you? | <input type="checkbox"/> | <input type="checkbox"/> |
| • Do you understand what this study is about? | <input type="checkbox"/> | <input type="checkbox"/> |
| • Have you had enough time to think about and discuss the study? | <input type="checkbox"/> | <input type="checkbox"/> |
| • Do you understand it's ok to stop taking part at any time? | <input type="checkbox"/> | <input type="checkbox"/> |
| • Are you happy to take part? | <input type="checkbox"/> | <input type="checkbox"/> |
| • If you are 12 years old or over and your parents agree, are you happy for us to contact you via text/email to complete the study questions? <i>(only asked if child contact details have been provided and the parent agrees on the parent/guardian consent form)</i> | <input type="checkbox"/> | <input type="checkbox"/> |

If any answers are 'No' or you don't want to take part, don't write your name!

If you **do** want to take part, please sign your name below:

Your Name _____

Your signature _____

Today's Date _____

Statement of person conducting assent discussion:

- I have explained all aspects of the study to the participant to the best of his or her ability to understand.
- I have answered all the questions from the participant relating to this research.
- The participant agrees to be in the research.
- To the best of my knowledge, the participant's decision to enrol is voluntary.

The study doctor and study staff agree to respect the participant's physical or emotional dissent at any time during this research when that dissent pertains to anything being done solely for the purpose of this research.

Printed name of the person obtaining assent

Signature of the person obtaining assent

Date