

## Trial of treatment of severe ankle sprains

This hospital is taking part in a study to determine the best treatment of ankle sprains. We would like to invite you to participate in this trial.

The trial is looking at four different treatments, which are explained in the accompanying leaflet. People taking part would be allocated randomly to these four treatments.

The doctor who sees you today will explain about the trial. Treatment today will not be affected by the trial, as it is the same for everyone, whether participating in the trial or not. You will also be given a leaflet. Please read this leaflet carefully.

If you are prepared to take part in the trial we would arrange to see you in 2-3 days time. A physiotherapist would then explain the trial in more detail and you would have the opportunity to ask more questions. If you agree the physiotherapist would then start your treatment.

Your treatment will not be affected if you do not wish to participate in the trial.

Thank you for considering taking part.

## **Study title: Study of four ways of treating severe ankle sprains**

*You are being invited to take part in a research study. Before you decide it is important for you to understand why the research is being done and what it will involve. Please take time to read the following information carefully and discuss it with others if you wish. 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.*

*Thank you for reading this.*

### **What is the purpose of the study?**

*This study aims to determine the best treatment for severe ankle injuries. We are comparing four treatments - a simple elastic bandage as is commonly used at present, a plaster of Paris cast, a plastic splint and a boot like support.*

### **Why have I been chosen?**

*All patients attending this hospital, and several others, with your type of injury are being invited to take part in this trial. Eventually 1800 patients will be taking part.*

### **Do I have to take part?**

*It is up to you to decide whether or not to take part. If you do decide to take part you will be given this information sheet to keep and asked to return to a clinic in 2-3 days time. At that clinic you will be given a further explanation of the trial and have an opportunity to ask questions. If you agree to participate in the trial you will be asked to sign a consent form. If you decide to take part you are still free to withdraw at any time and without giving a reason. A decision to withdraw at any time, or a decision not to take part, will not affect the standard of care you receive. If you decide not to take part the researcher may ask you why, but you do not have to answer this question.*

### **What will happen to me if I take part?**

*When you attend the clinic you will be given the opportunity to ask further questions before deciding whether you want to take part in this trial. If you decide to participate you will be allocated to one of the four treatments and given appropriate instructions and advice. We do not know which way of treating patients is best, that is why we need to make comparisons. People will be put into groups and then compared. A computer using an approach similar to tossing a coin selects the groups. Patients in each group then have a different treatment and these are compared.*

*At the clinic appointment, a short examination of your ankle will be performed and you will be asked to complete a short questionnaire with the help of the research physiotherapist. This will take about 30-45 minutes. Your further treatment will then be explained.*

*At about 12 weeks after injury, we will send you another copy of the questionnaire by post and would like you to complete this and post it back to us (we pay the postage). This will then be repeated 9 months after your injury. The researcher may contact you by phone soon after you receive the questionnaire to see if you need help completing it.*

### **What do I have to do?**

*We will give you advice on what exercise you can undertake whilst in the trial. If you still have problems after 6 weeks we will arrange further treatment for you, although*

*this will not be part of the trial. This will be standard treatment by the NHS. During the trial we will ask you to make note of certain events such as when you return to work or to playing sport.*

**What is the treatment that is being tested?**

*The four different treatments are:*

- An elastic bandage worn during the day*
- A plaster of Paris cast, like used when people break a bone*
- A plastic splint that supports the side of the ankle*
- A boot that looks like a ski boot that supports the ankle but has a hinge to allow movement*

**What are the side effects of any treatment received when taking part?**

*We do not know of any side effects from these treatments. Anybody with an ankle injury can develop severe swelling, and occasionally this can affect the circulation in the leg. By the time you receive one of the trial treatments the swelling should be going down. There is a small risk that the swelling could worsen or cause problems when the treatment is applied. If the pain worsens after your treatment is started or your foot becomes numb then you should contact the A&E department immediately.*

**What are the possible disadvantages and risks of taking part?**

*We do not know which of these treatments gives the best results. The only risk that we know of is the swelling mentioned above.*

**What are the possible benefits of taking part?**

*We hope that the treatments will help you. However, this cannot be guaranteed. The information we get from this study may help us to treat future patients with severe ankle sprains.*

**What if new information becomes available?**

*Sometimes during the course of a research project, new information becomes available about the treatment that is being studied. If this happens, your research physiotherapist will tell you about it and discuss with you whether you want to continue in the study. If you decide to withdraw your physiotherapist will make arrangements for your care to continue. If you decide to continue in the study you will be asked to sign an updated consent form. Also, on receiving new information the research physiotherapist might consider it to be in your best interests to withdraw you from the study. He/she will explain the reasons and arrange for your care to continue.*

**What happens when the research study stops?**

*You will be continuing with the treatment for 6 weeks. If you are still having problems at this time, we will arrange for you to have an appointment with an appropriate specialist to continue your care.*

**What if something goes wrong?**

*If taking part in this research project harms you, there are no special compensation arrangements. If you are harmed due to someone's negligence, then you may have grounds for a legal action but you may have to pay for it. Regardless of this, if you wish to complain, or have any concerns about any aspect of the way you have been*

*approached or treated during the course of this study, the normal National Health Service complaints mechanisms is available to you.*

**Will my taking part in this study be kept confidential?**

*All information that is collected about you during the course of the research will be kept strictly confidential. Any information about you that leaves the hospital will have your name and address removed so that you cannot be recognised from it. We would like to inform your general practitioner of your involvement in this trial, so that he is fully aware of your situation. We will confirm that you are prepared for us to do this, when you see the physiotherapist in the clinic.*

**What will happen to the results of the research study?**

*This study is expected to last three years. At the end of the study we will publish the findings in medical journals and at medical conferences. We will also put the results on the trial website. No individual patient will be identifiable in any results.*

**Who is organising and funding the research?**

*The National Health Service funds this study. The research team will receive salaries from the grant but these do not depend on the recruitment of patients or on the results that are produced. The study is being organised by the Universities of Warwick and Coventry.*

**What will happen if I decide not to participate in the research study?**

*If you decide not to participate in the research study you will be treated using the standard treatment used at your hospital that is elastic bandaging and provision of a pair of crutches with follow-up arranged by the A&E department.*

**Who has reviewed the study?**

*Your local research ethics committee has reviewed this study. If you have any concerns you may contact them on [to be inserted]*

**Contacts for Further Information**

*If you would like further information please contact the local researcher XXXXXXXXXXXX on telephone number XXXXXXXXXXXX. Alternatively, you can speak to Dr Cooke, who is leading the project by telephoning 02476 572905.*

*Please keep this information sheet for your future use. If you join the study, you will also be given a copy of your consent form.*