FixDT
UK Fixation of Distal Tibia Fractures

Chief investigator: Professor Matt Costa

PATIENT INFORMATION SHEET

We would like to invite you to take part in our research study, investigating two different ways of fixing your broken leg. This study will provide us with information which may help improve treatment of patients with similar injuries in the future.
Before you decide to take part we would like you to understand why the research is being done and what it would involve for you. A researcher from our team will go through the information sheet with you and answer any questions you have.

Background information
You have broken (fractured) the lower part of your shin bone. This part of the bone is called the 'distal tibia'. There are several treatment options for this injury. Sometimes the broken bone can be held in a plaster cast. However, the majority of fractures to the distal tibia require surgery and yours is one of those fractures.

During surgery, the bone is most commonly fixed in place with a metal device which is under the skin. This device can sit inside the hollow part of the distal tibia (a 'nail') or can sit on the surface of the bone (a 'plate').

Both plates and nails are successfully used in hospitals throughout the UK for patients with injuries like yours. However, there is little evidence from research studies to say if one is better than the other.

This study will compare plates versus nails with regards to the time required for the bone to heal, ankle function and quality of life. It is important to perform a study in which the two methods are compared, so in the future individuals with similar injuries will receive the best possible treatment.

What is the purpose of this study?
This study aims to determine the best treatment for patients with a fracture of the distal tibia. We are comparing two treatments – nail fixation versus plate fixation.

Why have I been chosen?
You are chosen because you sustained a fracture of the distal tibia which required surgery to fix the bones back into place. Over 20 hospitals across the country are taking part in this study

and a minimum of 320 patients will take part.

Do I have to take part?

It is up to you whether or not to take part. If you decide to take part you will be given this information sheet to keep and 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.

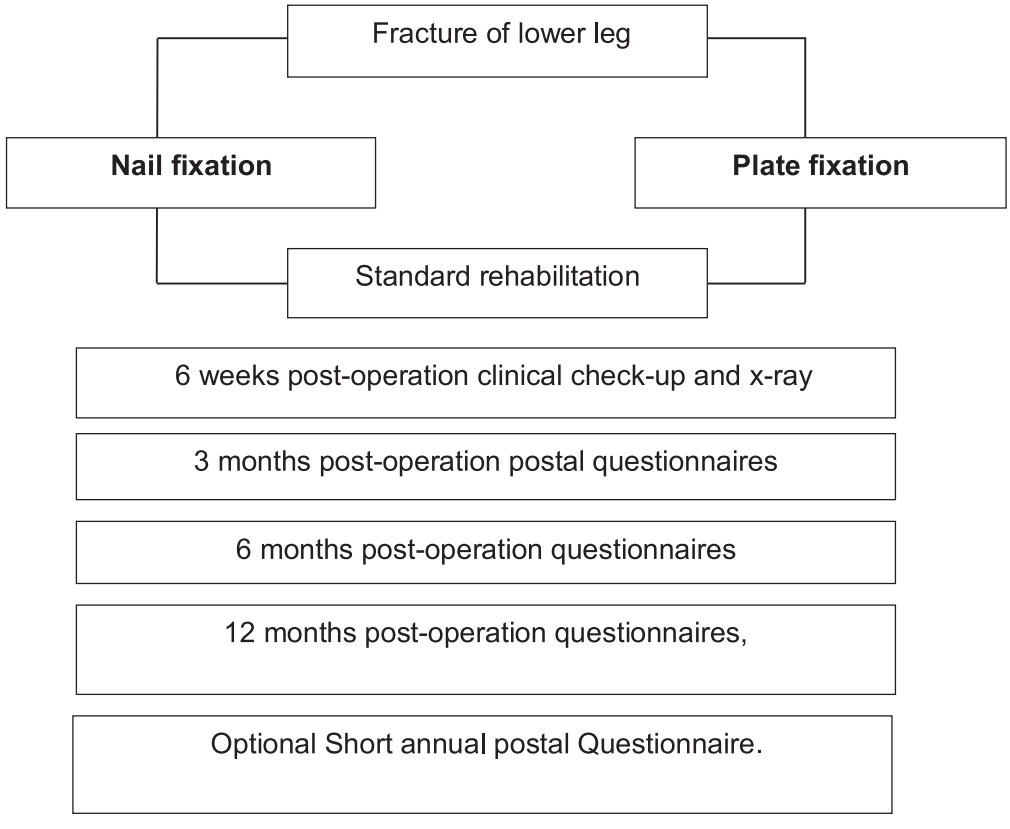
Which treatment will I be given?

You will be allocated to either a nail or plate fixation. The allocation process will be done by a computer and is done purely by chance. There is an equal chance of you receiving either the nail or plate fixation. The research associate will be able to tell you which type of fixation you will receive.

What will happen now?

All patients with a fracture of the leg are followed up carefully to make sure their fracture is healing during the first year after their injury. You will be followed up in the usual way. The only additional commitment we would ask of you for purpose of the research is to fill out a number of questionnaires to tell us about your recovery after your injury.

In the flow-chart below you can see a schedule of the visits / assessments and what would happen during this first year after injury.



If you decide you would like to be involved in the research study, you will be asked to sign a consent form after which we will ask you to fill out the first questionnaire. The questionnaire will ask you about how well you were able to perform certain day-to-day activities and how you were feeling before your injury occurred. The questionnaire will take approximately 10 minutes to complete. We will ask you to complete a similar questionnaire approximately 3, 6 and 12 months after your operation. At 3 months we will send the questionnaire to you in the post (with a free post return envelope), at 6 and 12 months it will be completed during your routine clinic appointment. A further shortened annual questionnaire will be sent to you in the post, if you consent at outset, for the long term follow up. With your permission, we may occasionally phone or send you a mobile text message to inform you a questionnaire is due or on its way to you.
All of the patients in the study will be invited back to their hospital for their final routine x-ray one year after their injury.
Appropriate personal identifying information will be collected, stored and used by the University of Warwick Clinical Trials Unit to enable the follow up of participants in the study. A copy of the consent form will also be collected by the Warwick Clinical Trials Unit for monitoring purposes. Any information will be treated with the strictest security and confidentiality.

What are the possible disadvantages and risks of taking part?
There are no specific risks of having one type of fixation or the other. Both treatments involve surgery which carries some risks, but the risks are the same and equal to individuals who do not take part. The risks of surgery include: risk of bleeding, risk of deep vein thrombosis, risk of damage to nerves and blood vessels in the surgical area and risk associated with the anaesthetic.

What are the possible benefits of taking part?
Both nail fixation and plate fixation are widely used for people with fractures of the distal tibia. There is no specific advantage to you for taking part in the study. However, the information we get from this study will help us improve treatments for future patients with similar fractures.

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 nurse will tell you about it and discuss with you whether you want to continue in the study. If you decide to withdraw, we will encourage you to discuss your continued care with your doctor. If you decide to continue in the study you will be asked sign an updated consent form.

What happens when the research study ends?
You will be in the study for 12 months. If you are still having problems after this time, your surgeon will arrange for you to have an appointment with an appropriate specialist to continue your care.

What happens if something goes wrong?

In the unlikely event that something does go wrong and you are harmed during the research and this is due to someone's negligence then you may have grounds for a legal action for compensation against the University of Warwick. Please address your complaint to the person below who is a senior University of Warwick official entirely independent of this study:

XXXX
XXXX
XXXX

or UHCW NHS Trust (Mrs Ceri Jones, R&D services manager, XXXX), but you may have to pay your legal costs. The normal National Health Service complaints mechanisms will still be available to you.

For independent advice contact the PALS service (Patient Advice Liaison Service) on XXXX

Will my taking part in this study be kept confidential?

All information which is collected about you during the course of the research will be kept strictly confidential. Any information about you which leaves Warwick Clinical Trials Unit will have your name and address removed so that you cannot be recognised from it. Your GP and other doctors who may treat you but are not part of this study will be notified, with your consent, that you are taking part in this study.

What will happen to the results of the research study?

The main trial is expected to last 5 years. At the end of this time we will publish the findings in medical journals and at medical conferences. You will not be identified in any reports or publications resulting from the study. If you would like to obtain a copy of the published results, please ask a member of the research team.

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

If you decide not to participate in the research study your care will not be affected and you will be followed up in the usual way.

Who has reviewed this study?

This study has been reviewed by the *West Midlands – Coventry and Warwickshire Research Ethics Committee* and approval was given on 06 November 2012.

Contacts for further information

If, at any time, you would like further information about this research project you may contact

Mrs Katie McGuinness, the trial coordinator of this research study, by telephoning XXXX.

Or you can contact your local Trauma Research Team, telephone number XXXX
The study is funded by the Department of Health and coordinated by University of Warwick Clinical Trials Unit. Professor Matthew Costa, who is the overall lead for this study may also be contacted on: XXXX.

Thank you for considering participation in this study and for taking time to read this information sheet.