<<<TO BE PRINTED ON LOCAL HEADED PAPER>>>

Distal Radius Acute Fracture Fixation Trial

Chief investigator: Mr Matt Costa

PATIENT INFORMATION SHEET

We would like to invite you to take part in our research study. Before you decide we would like you to understand why the research is being done and what it would involve for you. One of our team will go through the information sheet with you and answer any questions you have.

Contacts for further information

If, at any time, you would like further information about this research project you may contact your local research lead <<insert name of local researcher>> telephone number <<insert telephone number>> or the overall trial coordinator << insert name of trail coordinatior>> by telephoning <<insert telephone number>> or Mr Matthew Costa, who is the overall lead of this study on 02476 869618.

For independent advice contact the PALS service (Patient Advice Liaison Service) at freephone 0800 0284203.

What is the purpose of this study

You have sustained a fracture of the distal radius, which is the largest of the bones that form the wrist joint. Some fractures of the distal radius can be treated in a plaster cast. However, other fractures of the distal radius are 'displaced' and need to be manipulated back into their original position and then held in that position until they have healed. The operation to hold the bone in its best position is called a 'fixation'.

There are several different forms of fixation for fractures of the distal radius. The two most comon forms of fixation in the NHS are 'K-wire fixation' and 'plate and screw fixation'. Both types of fixation are used successfully in thousands of patients in the UK each year. However, we do not know which type of fixation provides the best wrist function for patients with a fracture such as yours. It is therefore important to perform a study in which the two methods are compared, so that in the future individuals with similar fractures will receive the best possible treatment.

This study aims to determine the best treatment for patients with a fracture of the distal radius. We are comparing two treatments – K-wire fixation with plate and screw fixation.

Why have I been chosen?

You have been chosen because you have sustained a displaced fracture of the distal radius which your surgeon feels would benefit from an operation to fix the bone back into position. Approximately 10 hospitals across the country will take part in this trial and a total of 390 patients will be recruited.

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 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.

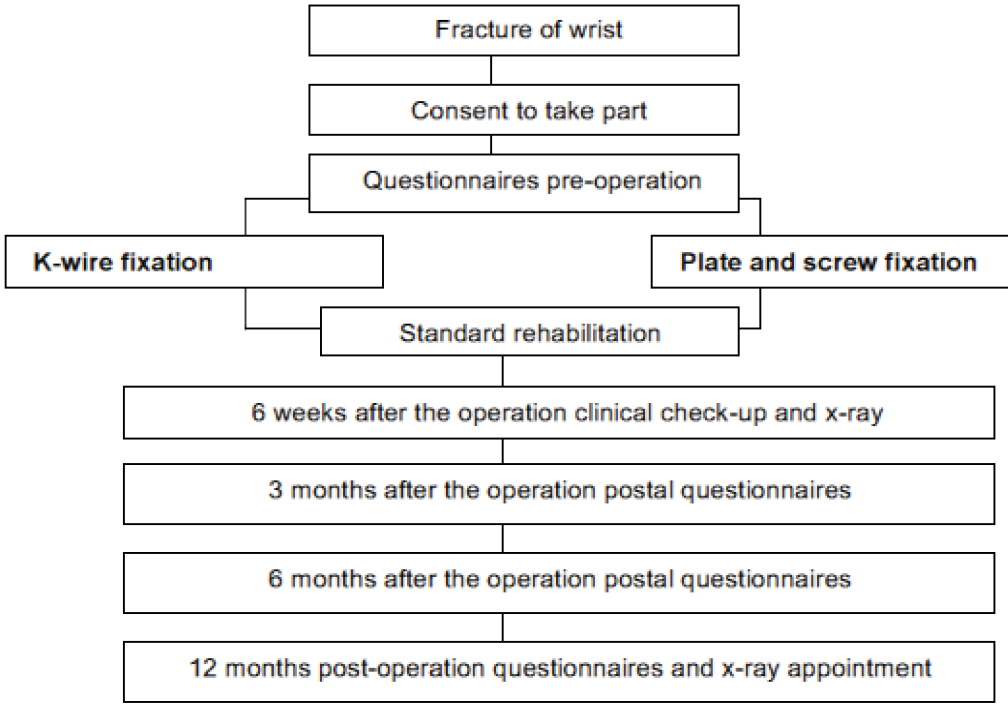
Which treatment will I get?

If you agree to take part, you will be allocated to either the K-wire group or the plate and screws group. The allocation process will be done by a computer and will be done purely by chance. There will be an equal chance of you receiving either K-wire fixation or plate and screw fixation.

To answer the question set out in the purpose of this study, we will compare the results we get from one treatment group with the results from the other group.

What will happen after I have been placed in one of the two groups?

In the flow-chart below you can see a schedule of the visits/assessments and what would happen at each time-point.



Once you have agreed to take part and given us your informed consent, you will be asked to fill out some questionnaires. The questionnaires will ask you about how well you are able to perform certain day-to-day tasks and how you feel. They will take 5 to 10 minutes to complete.

Your operation will be booked for you in the usual way. Both types of fixation require a general anaesthetic so you will be 'asleep' during the surgery. If you are allocated to the K-wire group the wires will be passed across the fracture on the back of your wrist. If you are allocated to the plate and screws group the plate will be screwed to the surface of the bone on the palm side of your wrist. Both types of operation are performed routinely in your hospital but the exact details of the surgery will be decided by your surgeon according to their preferred technique.

For the purpose of this study we would like to follow you up for one year after your operation. Your surgeon will arrange to see you at 6 weeks after the operation for a check up and an x-ray in the usual way. We will then send you some questionnaires in the post at 3 months, 6 months and 1 year after your operation: these will be the same questionnaires that you did before the operation and we will provide you with a stamped-addressed envelope to send them back to us once you have filled them out. All of the patients in the study will then be invited back to their hospital for a final x-ray one year after their injury. Your surgeon may of course arrange other visits to your hospital if he/she feels these are necessary.

What are the possible disadvantages and risks of taking part?

Both types of fixation in this study involve surgery. With any operation around the wrist there is a risk of infection, bleeding, failure of the fixation and damage to the nerves, blood vessels or tendons around the wrist. The risks of the surgery are the same for both groups of patients in the study and are the same as for patients who are not taking part in the study.

What are the possible benefits of taking part?

Both K-wire fixation and plate and screw fixation are used across the NHS for patients with a fracture of the distal radius so there is no specific advantage to you for taking part in the study. However, the information we get from this study may help us to treat 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, the research team will tell you about it and discuss with you whether you want to continue in the study. If you decide to withdraw, we will make arrangements for your care to continue. 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, we will arrange for you to have an appointment with an appropriate specialist to continue your care.

What happens if something goes wrong?

In the 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 (Mr Peter Hedges, Director of Research Support Services, 02476523716) and/or UHCW NHS Trust (Mrs Ceri Jones, R&D services manager, 0247696196), but you may have to pay your legal costs.

The normal National Health Service complaints mechanisms will still be available to you

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 the research centre 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 that you are taking part in this study.

What will happen to the results of the research study?

This study is expected to last 3 years. At the end of the study 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 your doctor.

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 may discuss your further treatment with your doctor.

Who has reviewed this study?

This study has been reviewed by the Coventry Research Ethics Committee and approval was given on xxxth of xxx 2010.