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Patient Information Sheet

PROximal Fractures of the Humerus: Evaluation by Randomisation
The PROFHER trial

A UK multi-centre study of surgery for displaced fractures at the top end of the upper arm bone

(Reference number: 08/H1311/12)

We would like to invite you to take part in this research study. Before you decide, it is important for you to understand why this research is being done and what it would involve for you. 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?

Your doctor will have told you that the top end of your upper arm bone (humerus) has broken (fractured) near the shoulder joint. These fractures are common injuries, particularly in older people. The less serious fractures are treated by supporting the arm in a sling to help the bone to heal enough to allow movement. This is followed by exercises.

About half of these fractures are more serious because the parts of the bone are displaced from each other. Such fractures are more difficult to treat and the surgeon may consider that an operation would be helpful. Surgery often involves putting the fractured parts together again and fixing them in place with various devices such as nails or plates. Sometimes the top end or head of the humerus is replaced by an artificial joint. However, for the majority of serious fractures surgeons are not sure whether an operation is better than supporting the arm in a sling and leaving the bone to heal. This is because there is no strong evidence that surgery gives a better result.

The aim of this UK multi-centre trial is to find out whether people with these more serious fractures do better if they have an operation within a few days of their injury. Surgeons and others, including people who have had these injuries, have agreed that the best way to find this out is to conduct a randomised trial. This means that the surgeon and patient agree to use whatever treatment (surgery or no surgery) is selected at random (or by chance). This is the best way to ensure that the two treatment groups are similar at the start. The results of this trial are likely to influence how these fractures are treated in this hospital and more generally in the future.

Why am I being asked to take part?

You have been invited to enter this trial because you have a serious break (fracture) at the top end of your upper arm bone. Your surgeon feels that you are fit enough for an operation but does not know if you would have just as good a result if you didn't have surgery.

Do I have to take part?

No. It is up to you to decide. You are free to withdraw at any time, without giving a reason. This would not affect the standard of care you receive.

What will happen to me if I take part?

After signing the consent form, you will be asked a few further questions. Then you will find out whether you have been allocated to surgery or not. In this trial there is an equal (or 50:50) chance of being allocated to surgery or no surgery.

You will then receive the allocated procedures delivered with the same standard of care that you would receive if you were not in the trial.

Thus, if you are allocated surgery, your surgeon will discuss with you the type of surgery he or she recommends for you. Your operation will be carried out by an orthopaedic surgeon experienced in treating shoulder fractures. Your surgeon will advise about the best care of your arm after your operation. Usually you will keep your arm in a sling for about three weeks. This will be followed by exercises.

If you are allocated to no surgery, your surgeon will again advise about the best non-operative treatment for you. Usually you will keep your arm in a sling for about three weeks, followed by exercises.

The only other thing that we ask of you is to complete a short questionnaire at three months and a longer one at six months, one year and two years after your injury. These questionnaires are very important and should not take longer than fifteen minutes to complete. You can ask a friend or relative to help you with these. A pre-paid envelope will be included. The information you give will be treated as confidential and only used for the trial.

You will need to tell us if you are happy for us to text you via your mobile number, if you have one. This would only be used to inform you of when to expect a questionnaire.

With your permission, we will inform your family doctor that you are taking part in the trial. Again with your permission, if we have difficulties contacting you we would like to ask your family doctor about whether it is appropriate to contact you and for your address.

We will also collect data from the hospital. Initially, this will be what treatment you received in hospital for your fracture and whether you have any complications. We will also ask the hospital to check their records after one and two years in case you had any later problems.

When we contact you at two years we will also ask if you would like to know the results of the trial when these become available.

What are the alternatives to taking part?

If you choose not to take part then your surgeon will discuss with you the options available for your treatment. It is possible that your surgeon may advise you to have surgery. Whatever you decide about taking part in the study it will not affect the standard of care you receive.

What are the possible disadvantages of taking part?

While the selection of treatment, surgery or no surgery, is left to chance you will receive the same standard of care as you would normally. The surgeon and other people providing your care are experienced in the treatments provided. There are no new treatments being tested in this study.

However, because all surgery involves extra risks, such as infection, it is very important that you consider whether you would be prepared to have surgery. You should also consider though that surgery may give you better shoulder function and may mean that you can be more independent. Sometimes too, surgery may be needed to correct problems later on. Such surgery is often more difficult to do and you may have a long wait.

If you receive an operation, you will usually be given a general anaesthetic. Although general anaesthesia is very safe with modern techniques, there are still very small risks involved. You may experience nausea, vomiting and / or dizziness. These are reduced with modern drugs. It is important that you tell the research team, medical staff and anaesthetist about any medical problems you have.

There is also a small chance of developing a wound infection. The exact risk is not known but most resolve with antibiotics. Occasionally, the metal implant may need to be removed. This will involve another operation. Another operation may also be needed if the fixation fails. For example, movement of the metal implant or parts of the implant may cause problems such as restricted movement and pain. Again, the exact risk of this happening is not known. You can be assured though that your surgeon will use devices with low complication rates and with which they are familiar.

It is important to realise that there are risks and problems for non-operative treatment too. If you don't have surgery, it may take longer for you to recover. It will mean that the fragments of bone will not be put back in place. This means that while the bone may heal, it will not be as it was before. This may give problems such as restricted movement and pain. You may start getting other shoulder problems too. Sometimes, these difficulties are bad enough to make you more dependent on the help of others. If this occurs, an operation may sometimes help. But because it is not a fresh fracture and other damage may have occurred, the surgery involved is usually more complex.

For both operative and non-operative treatment, some problems take a while to show themselves. This is why we ask people to tell us how they and their shoulder are at two years.

What are the possible benefits of taking part?

Because we do not know what treatment is best you might not benefit from taking part but by taking part you may help others in the future. We believe though this study has already increased awareness of injuries such as yours and recognition of the need for good quality care. If enough people take part in this study, the information we get should help ensure that people with these injuries have the best treatment in the future.

What will happen if I don't want to carry on with the study?

You are free to withdraw from the study at any time. You do not have to give a reason for this. Withdrawing will not affect your future care or rights in any way. It is up to you whether you tell us. However, if you do let us know of your decision then we will know not to contact you in future. It is also up to you to tell us whether you would prefer that we didn't contact the

hospital for any further outcome data and whether you would like your contact details to be deleted from the records. All the other data collected for you up to the time of your withdrawal from the study will be kept.

Expenses and payments

This trial is funded by the NHS and involves you in no extra treatment or tests. Thus no patient expenses have been allocated. However, in recognition of your help with this trial you will receive an unconditional payment of five pounds at one and two years after your injury when asked to complete questionnaires.

What will happen to data that are collected about me?

Your data will be held in a secure place in the co-ordinating centre in University of York. All data for the trial will be held for a minimum of 20 years. We will remove all names and other identifying information before the data are analysed and results of the trial presented to the medical community.

What happens if something goes wrong?

This trial only includes treatments that you would receive normally. The clinicians treating you will take every opportunity to reduce risk. If something were to go wrong, they will offer the best possible solution to resolve it. If you believe that you have been harmed in any way by taking part in this study, you have the right to pursue a complaint through the usual NHS procedures. Details about this will be available locally.

Who has reviewed this study?

Before any research goes ahead it has to be checked by a Research Ethics Committee. They make sure that the research is fair. This project was passed through the National Research Ethics Service as well as the local Ethics Committee for your hospital.

Who is organising and funding this research.

This trial is funded by the NHS R&D Health Technology Assessment Programme. The sponsor is the University of Teesside, Middlesbrough. Trial management is by the York Trials Unit (YTU), University of York. This trial has received endorsement by the British Elbow and Shoulder Society.

None of surgeons involved will receive payments for their involvement in the trial. The hospitals receive payments for entering a patient into the trial but these only cover the extra expenses incurred by the hospital for helping with this trial.

Who can I contact for more information?

If you have any queries or you wish to obtain further information about this study, please contact [designated local contact] on [telephone]. Alternatively you may contact Dr Stephen Brealey (PROFHER Trial Co-ordinator) on 01904 [redacted].

Thank you for reading this information sheet and for considering whether to take part in this study.