ProFHER-2

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Patient Information Sheet

Effectiveness and cost-effectiveness of Reverse Shoulder Arthroplasty versus Hemiarthroplasty versus Non-surgical care for acute 3 and 4 part fractures of the proximal humerus in patients aged over 65 years – The PROFHER-2 Randomised Clinical Trial

HTA Project Reference number: 16/73/03

We would like to invite you to take part in a research study

- Before you decide on whether you wish to take part, 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 before you decide.
- Ask us if there is anything that is not clear or if you would like more information.
- Thank you for reading this information about the research study.

Important things that you need to know

- We want to find the best way to treat people who have a serious break (fracture) at the top end of the upper arm bone near the shoulder where the bone is broken into more than two 'parts' (3 or 4 parts).
- There is not a currently understood "best" treatment for this type of fracture, and this is the purpose of the study.
- We are testing the use of three commonly used treatment options for fractures of this kind, which are two types of joint replacement surgery or structured non-surgical treatment.

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Contacts

If you have any questions about this study, please talk to your doctor and research nurse who organise it:

Principal Investigator: [Insert name & contact number]

Research Nurse:[Insert name & contact number]

PROFHER 2 This project was funded by the National Institute for Health Research Health Technology Assessment Programme (Project number 16/73/03)

1 Why are we doing this study?

What is the purpose of the study?

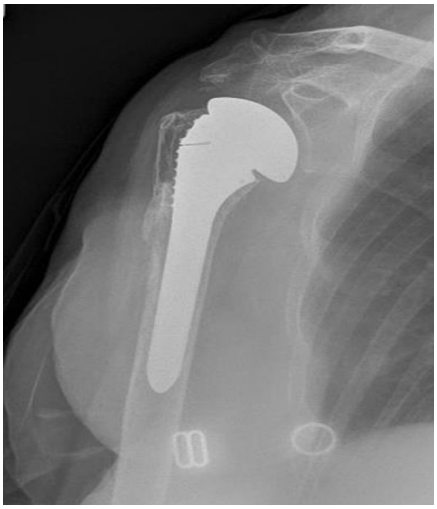
The aim of this UK-wide study is to find the best way to treat people who have a serious break (fracture) at the top end of the upper arm bone near the shoulder where the bone is broken into more than two parts. There is not a currently understood “best” treatment for this type of fracture, and this is the purpose of the study. We are testing the use of three commonly used treatment options for fractures of this kind, which are two types of joint replacement surgery or structured non-surgical treatment. We are speaking to you now because you have one of these types of fracture.

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 people over 65 years of age. The less serious fractures are usually successfully treated by supporting the injured arm in a sling until the fracture heals, followed by exercises. Some fractures are more serious and complex when the bone is broken into more than 2 parts. Such 3 and 4 part fractures are more difficult to treat.

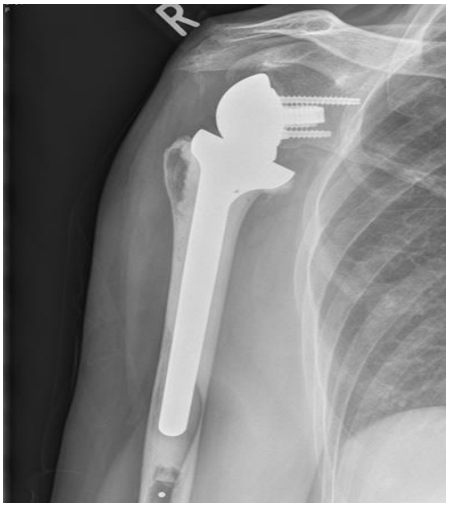
Your doctor may consider treating the fracture without surgery in a sling to allow fracture healing followed by structured physiotherapy with exercises to regain use of the arm; or with surgery to replace the broken bone with an artificial shoulder joint

There are two main types of joint replacement surgery used: ‘Hemiarthroplasty’, which involves replacing only the broken 'ball' of the joint (top end of the arm bone), or ‘Reverse Shoulder Arthroplasty” which replaces both the ball and socket, but replaces the ball with a socket and the socket with a ball (hence ‘reverse’). Use of the reverse method is increasing. Following each of these treatments, good physiotherapy is needed to regain arm function.

Hemiarthroplasty



Reverse Shoulder Arthroplasty



Non-surgical treatment has the advantage of avoiding the risks of surgery but it is uncertain whether recovery is as good as with surgery. There needs to be good quality research to assess which is the most effective treatment. Doctors therefore remain unsure about how best to treat the more severe fractures. They do not know which type of joint replacement leads to the best recovery and also whether replacing the shoulder joint is better than structured nonsurgical care (supporting the arm in a sling and leaving the bone to heal naturally, followed by physiotherapy).

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The aim of this UK-wide study is to find out whether Reverse Shoulder Arthroplasty is more effective than Hemiarthroplasty at restoring use of the shoulder and arm in patients with the most severe fractures. The study will also investigate whether either type of surgery is more effective than non-surgical treatment for these fractures.

The best way to find this out is to conduct a randomised trial. This means that you and your doctor agree to use the treatment selected at random (or by chance) by a computer system. You may receive one of the two types of shoulder joint replacement surgery or non-surgical treatment, which will be chosen for you at random. In this trial, there is an equal chance of you being allocated to any of the three treatments (the two types of surgery or no surgery). 380 patients will be taking part in this national study. The results of this study are likely to influence how these fractures are treated in the future.

With some of these fractures, the shoulder joint may be 'dislocated', where the ball of the joint moves away from the socket and these injuries are termed 'fracture dislocations'. These associated joint 'dislocations' need to be manipulated back into their original position (reduced). The doctors will attempt a closed (without making any incisions in the skin) reduction of these fractures. The manipulation can be painful therefore this will be carried out under sedation or sometimes may need a general anaesthetic. If you have a fracture dislocation that needs a general anaesthetic for the dislocation to be reduced, your doctor and research team will let you know and you will receive one of the two types of shoulder joint replacement surgery chosen at random. Doctors usually consider treating this type of injury with surgery.

Why am I being asked to take part?

You have been invited to enter this study because you have a break (fracture) at the top end of your upper arm bone where the bone is broken into more than three parts.

Do I have to take part?

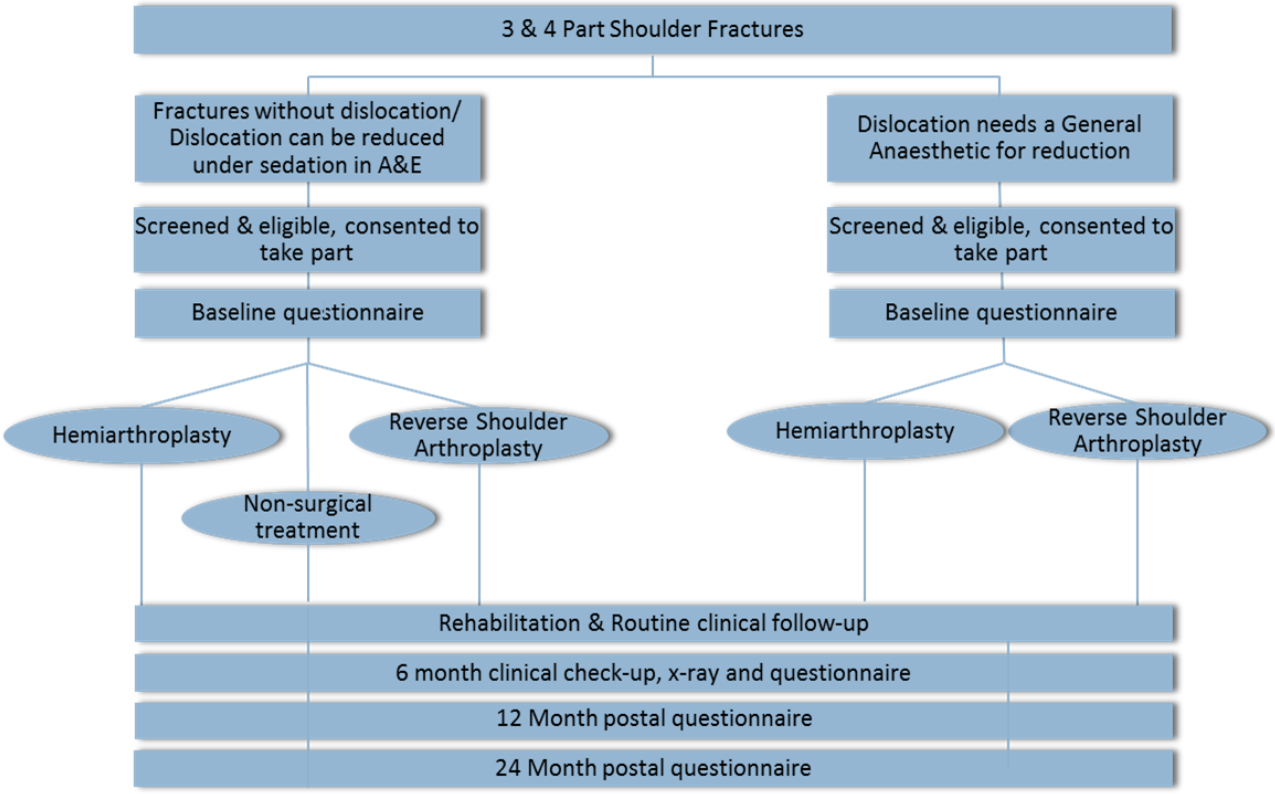
No. It is up to you to decide. You are free to withdraw at any time, without giving a reason. This would not affect the standard of care you receive.

What are the alternatives to taking part?

If you choose not to take part then you are likely to receive one of the treatments described above, but we will not collect any data about your treatment. Whatever you decide about taking part in the study, it will not affect the standard of care you receive.

2 What would taking part involve?

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 what treatment has been chosen at random for you. You will then receive the chosen treatment delivered with the same standard of care that you would receive if you were not in the trial. We will collect x-rays and information from your doctor on the treatment you receive. If you have been chosen to have surgery, your doctor will discuss with you the type of joint replacement surgery you will receive.

Your operation will be carried out by your treating doctor. Your doctor will advise about the best care of your arm after your operation. Usually you will keep your arm in a sling for about three to four weeks after the operation. This will be followed by physiotherapy. These physiotherapy sessions may be completed by telephone or video, and will be determined by local assessment of risk. If you have been chosen to have non-surgical treatment, you will keep your arm in a sling for about three to four weeks to allow initial healing of your injury, followed by physiotherapy. Once more, these physiotherapy sessions may be completed by telephone or video, or in person, and will be determined by local assessment of risk

Your doctor will arrange to see you for routine check-ups. You will be asked to attend a hospital follow up visit, where we will collect some data and have your x-rays taken at 6 months from entering the study. These visits may be completed by telephone or video, or in person. If appointments are carried out remotely, x-rays will not be taken at this point. We will also ask the hospital to check their records after one and two years in case you had any later problems.

In addition, we will ask you to complete a questionnaire at six months, one year and two years from entering the study. 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. Any personal information you give will be treated as confidential.

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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 may also collect relevant information held about the surgical treatment for your shoulder injury from other NHS bodies such as the National Joint Registry, Hospital Episode Statistics and other linked sources.

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.

3 What are the possible benefits of taking part?

Because we do not know what treatment is best you might not directly 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.

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

While the selection of treatment is randomised you will receive the same standard of care as you would normally. The doctor and other people providing your care are experienced in the treatments provided. There are no new treatments being tested in this study. We don't currently know which of the three treatments works best which is why we are conducting this study.

It is important to realise that there are risks and problems associated with both surgical and non-surgical treatment. However these risks are no different from those you would experience with these treatments if you were not part of the study. For both surgical and non-surgical treatment, some problems may take a while to show. This is why we ask people to tell us how they and their shoulder are at two years.

Irrespective of whether you receive surgical or non-surgical treatment you will be reviewed by your doctor and if another form of intervention is needed you will be offered this.

During the study we will take x-rays of your shoulder and x-rays at one of the follow-up time points maybe extra to those that you would have if you did not take part in this study. X-rays can cause cell damage that may, after many years or decades, turn cancerous. The chance of this happening to you as a result of taking part in this study is extremely small.

5 More information about taking part

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. If you do withdraw then we will know not to contact you in future. At this point we will ask whether you would prefer that we didn't contact the hospital for any further outcome data and whether you would like your personal details to be deleted from the records. We will also ask you if all the other anonymised data collected from you up to the time of your withdrawal from the study can be kept.

Will my taking part in the study cost me anything?

We will reimburse the cost of your travel to attend the 6-month hospital visit if this is not routine at your hospital. If you have been allocated to receive non-surgical care, your travel costs to attend up to 12 physiotherapy sessions will be covered as this may not be routine in your local hospital.

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.

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. X-ray images will be securely transferred to and stored at South Tees Hospitals NHS Foundation Trust. All efforts will be made to anonymise these images before transfer. All data for the trial will be held for a minimum of 15 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. PALS Details are:

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 study has been reviewed and given favourable opinion by Tyne and Wear South Research Ethics Committee (Reference: 18/NE/0125).

In addition, we have consulted with people who have experience of undergoing treatment for this type of fracture who have provided useful feedback on the study and the information provided from a patient's perspective.

Who is organising and funding this research.

This trial is funded by the NIHR Health Technology Assessment Programme. The sponsor is the South Tees Hospitals NHS Foundation Trust, Middlesbrough. Trial management is by the York Trials Unit (YTU), University of York. This trial is supported by the British Elbow and Shoulder Society. 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.

What will happen to the results of the research study?

The results from this study may be published in journals, presented at scientific meetings and media so other healthcare professionals caring for similar patients can learn from the results. However, you will not be identified in

any reports, publications or presentations. During your involvement, you will be asked whether you would like to be informed of the results of the study.

Information collected about you will be used to support other research in the future. Anonymised data that you provide may be shared with authorised researchers and third parties

6 How to contact us

Who can I contact for more information?

You may contact the Research and Development department at your hospital for more information about taking part in research

Email: Telephone:

If you have any queries or you wish to obtain further information about this study, please contact your Research Nurse. Their contact details are on the first page of this document. Thank you for reading this information sheet and for considering whether to take part in this study.