Glenfield Hospital
Groby Road
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PARTICIPANT INFORMATION SHEET

STUDY TITLE: A RANDOMISED CONTROLLED TRIAL TO DETERMINE WHETHER INJECTION PRIOR TO PHYSIOTHERAPY IMPROVES THE OUTCOME FOR MASSIVE ROTATOR CUFF TEARS AND WHICH MUSCLES ARE USED TO REPLACE THE ROTATOR CUFF IN PATIENTS WITH GOOD FUNCTION AND KNOWN MASSIVE CUFF TEAR

You are being invited to take part in a research study. Before you decide it is important for you to understand what the research will involve. Please take time to read the following information carefully and discuss it with others if you wish. Please make contact if there is anything that is not clear or if you would like more information (contact details below)

What is the purpose of the study?
The purpose of this study is to determine whether an injection of steroid and local anaesthetic changes the outcome of physiotherapy for patients with large/massive rotator cuff tears. We also want to study if the function of the muscles around your shoulder or the location of the tear influence your result.

Why have I been chosen?
You have been chosen as you have a large / massive rotator cuff tear, a painful shoulder, limited range of movement actively and are over 65 years of age.

Do I have to take part?
It is up to you to decide whether or not to take part. Please take your time considering whether you wish to participate. Taking part will not delay the normal treatment you would receive.

What will happen to me if I take part?
You will receive physiotherapy at the Glenfield Hospital. You will be invited to attend to have an injection, and will be randomised (that is the choice will be made as if tossing a coin) as to whether you receive local anaesthetic alone, or a combination of local anaesthetic and steroid, both are pain killers of different types used regularly around the shoulder. The treatment will be blinded that means neither you nor your treating physiotherapist will know what you have had.

Your physiotherapy treatment will commence one week after you receive the injection. The physiotherapy you receive is standard normal care, and how often you are seen will depend on the physiotherapist's assessment and how quickly you progress. You will be asked to fill in a questionnaire and have some measures made of the function of your shoulder(each of which only take about 5 minutes to complete before starting treatment, at 6 months or discharge from physiotherapy (whichever is sooner) and again at 12 months. A proportion of the participants will be asked to have Electromyography (EMG**:** a technique for evaluating and recording the electrical activity produced by skeletal muscles) before the physiotherapy starts and at the end of the physiotherapy about 6 months later. This will be the first 16 participants, and will involve 2 appointments at Glenfield Hospital.

The EMG sessions will involve two appointments about 6 months apart which will last about 1 hour. Small electrodes will be attached to the skin with sticky tape above a number of muscles around your shoulder to measure how well they are working. We will ask you to flex your muscles then do some simple tasks, for example lift a light weight. The tests should not hurt. EMG studies are regularly used in the hospital for the diagnosis of some conditions and as part of normal clinical care.

Your details will remain confidential. We may need to look at your medical notes but when recording information for the study we will do it via a coded number. Data will be stored in a confidential database which is password protected, only accessible to authorised individuals associated with the research.

What do I have to do?
If you say yes to the study, you will be required to attend physiotherapy at the Glenfield hospital, and complete the outcome measures(mentioned above) that the physiotherapist will go through with you pre treatment, at 6 months or discharge from physiotherapy (whichever is sooner) and at 12 months. If you are in the first 16 participants you will be asked to attend 2 appointments at Glenfield Hospital (pre physiotherapy / injection, and post physiotherapy). The physiotherapists will be asking you to complete home exercises, which is normal standard care for your treatment.

What are the possible benefits of taking part?
Hopefully you will be contributing to improving practice for the management of large rotator cuff repairs. The conclusions from this project will make suggestions for future practice and research.

What are the disadvantages of taking part?

The injection may cause you some level of pain in the short term. The injection may only give short-term relief.

There are very small risks (1 in 40,000) that as a result of the steroid and/or local anaesthetic injection you may get an infection. If this happened then you would need to see your doctor and come to hospital for the infection to be cleared. There is a very small risk that you may have an allergic reaction to the steroid or to the local anaesthetic (less than 1 in a 1000). If this happened this might cause swelling around your face and mouth, hands and feet, difficulty breathing or swallowing or itching of your skin. If it occurred, you would be given a drug to compensate for the reaction. Rarely you may get temporary facial flushing(from the steroid). Rarely it is possible that there may be a very mild temporary decreased function of the limb where the injection was given(from the local anaesthetic) lasting about 24 hours. Rarely you might have a faint(vasovagal episode) from the injection.

What will happen to the results of the research study?
The results will be analysed, presented to physiotherapists and doctors who look after patients like you and published in the journals. This will give direction for future research also.

What happens if I wish to withdraw from the Study?
You are free to withdraw from the study at any time. Your data can be destroyed or retained in the study according to your wishes

What if something goes wrong?

If you are not happy at any time you may raise your issue with the researchers or you can raise it through the trusts complaints mechanism. If you have any concerns about the study or your participation, you can contact the study team on 01162583595 or for independent advice you can contact University Hospitals of Leicester Patient Information and Liaison Service on 08081 788337.

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 hospitals of Leicester NHS trust but you may have to pay your legal costs. The normal National Health Service complaints mechanisms will still be available to you (if appropriate)

Who has reviewed the study?
All research that involves NHS patients or staff, information from NHS medical records or uses NHS premises or facilities have been given a favourable opinion by an NHS Research Ethics Committee before it goes ahead. Approval means that the committee is satisfied that your rights will be respected, that any risks have been reduced to a minimum and balanced against possible benefits and that you have been given sufficient information on which to make an informed decision. This study has been reviewed and given a favourable opinion by the Research Ethics committee.

CONTACT FOR FURTHER INFORMATION:

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Thank you for your time.