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Sub-acromial spacer for Tears Affecting Rotator cuff Tendons (START)

Chief Investigator: Mr Andrew Metcalfe

PATIENT INFORMATION SHEET

Funder acknowledgement:

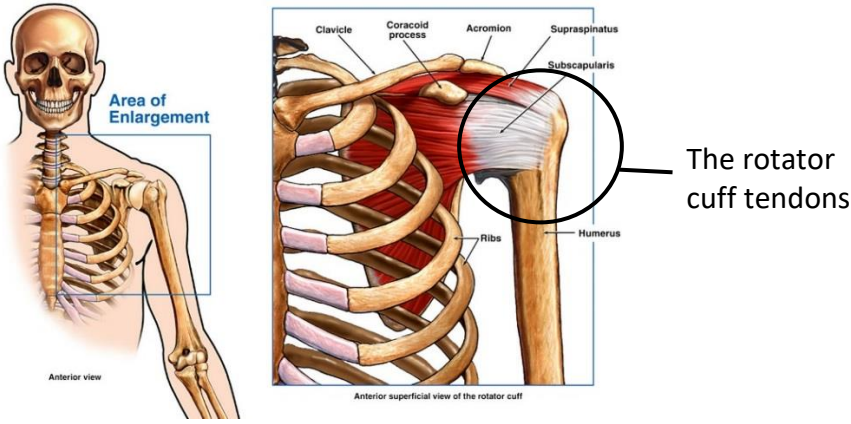
This study is funded by the National Institute for Health Research (NIHR) - EME Project: 16/61/18.

You are invited to take part in our research study. Before you decide whether to take part we would like you to understand why the research is being done and what it would involve for you.

Once you have read this information sheet a member of our team will go through the information with you and answer any questions you may have.

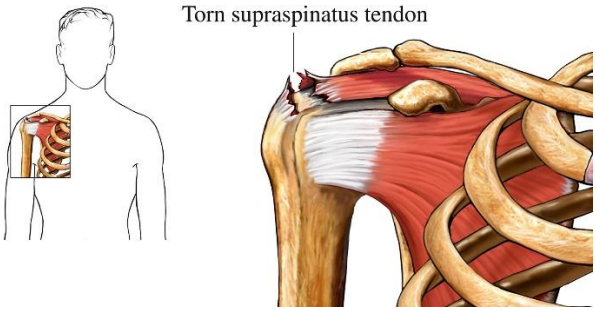
Background Information

Within your shoulder, there are a group of small muscles and tendons, called the 'rotator cuff'. Tears of the rotator cuff tendons are very common. They can be very painful and it can be difficult to move the shoulder normally.



Anatomy of the shoulder

Many tears of the tendons can be repaired but some tears cannot. When a tear cannot be repaired, one common treatment is a keyhole operation to clear space around the tendons and remove the painful tissue. This is called an 'arthroscopic debridement'. It is not known if this operation helps in every case, but it is low risk and is thought to benefit most people with rotator cuff tears.



A rotator cuff tear

A new device has recently been introduced in the UK with the aim of improving outcomes from surgery for this condition. It is a balloon made out of a biodegradable synthetic material (free of animal products), called the 'InSpace balloon'. It is inserted at the end of an arthroscopic debridement operation and is filled with water. It is thought to act as a cushion inside the joint. It dissolves after about three months, by which time you have a chance to strengthen the other muscles to give a longer lasting effect. It is not yet known if it is any better or worse than the standard arthroscopic debridement operation.

What is the purpose of this study?

The purpose of the study is to find out whether it is better to have an arthroscopic debridement operation, or the same operation with the addition of the 'InSpace balloon', when you have a tear of the rotator

cuff muscles that cannot be repaired.

The National Institute of Health and Care Excellence (NICE) has studied the balloon and decided that it should only be used in research to determine if it works.

We will look at which operation is best at reducing pain and improving movement, strength, and quality of life, and whether the balloon is worth the additional cost.

Why have I been invited?

Your surgeon thinks that that your shoulder pain, due to a rotator cuff tear that cannot be repaired, might be helped by an arthroscopic debridement. They are helping us to find out if using the 'InSpace balloon' improves outcomes from this surgery.

Do I have to take part?

It is up to you whether or not to take part. 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.

What will happen if I take part?

If you decide to take part you will be asked to sign a consent form. In order to make our study work it is crucial that we have equal numbers of participants in each treatment group.

To ensure this is fair, a computer will decide at random which operation you will have. To make the comparisons fair between the two operations, we will not tell you which operation you have had until the end of the study. When we publish the results, we will send you a summary of our findings and tell you which group you were in. This may be several years from now.

Whichever treatment you have, your care will be based on meeting your individual needs, and you will continue with the same team of surgeons and healthcare professionals.

Before the operation

You will be asked to complete a questionnaire about your shoulder and your general health, and a trained member of staff will take a measurement of the strength of your shoulder and how much pain-free movement you have.

During the operation

The surgeon will check that you are still suitable for the study. If the surgeon does not think you are suitable (for example, if they can repair the tendon), you will not be entered into the study and the surgeon will

do whichever operation they think is most suitable for you at the time. There will be no difference between the scars from the two operations and the balloon adds very little time to the operation itself. Photographs of the inside of the shoulder are routinely taken by the surgeon using the 'keyhole' camera during normal care. For this study, a copy of the photographs will be sent to researchers at the University of Warwick and the University Hospital Coventry and Warwickshire who will assess that the surgery has been done according to the recommended study technique.

After the operation (follow-up)

You will be given an advice and exercise sheet which explains what you will have to do after the operation. You will have a physiotherapy appointment booked and will need to attend a number of physiotherapy sessions.

You will be seen by the study team three months, six months and 12 months after the operation. Your surgeon may decide to see you at other times as well. At each of the three study visits, a member of staff will measure the strength and pain-free movement in your shoulder and will ask you to fill in a questionnaire. If you cannot complete the questionnaire in person, it will be posted or given to you and we will ask you to post it back in the freepost envelope provided. If you agree we can send you a text message or email to remind you that the

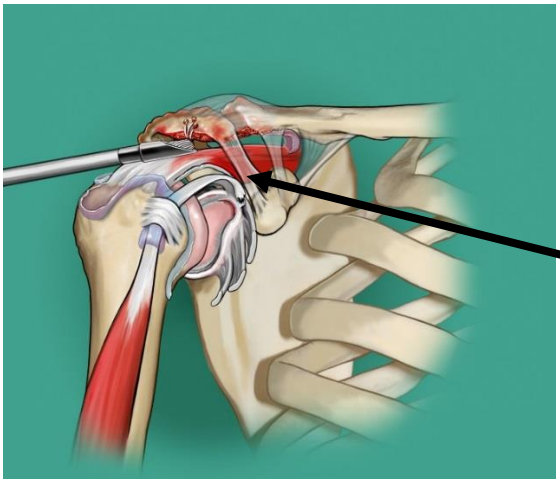
questionnaire is due. If you need help completing a questionnaire, a researcher can contact you by phone to help you complete it.

Two years after the operation we will write to you (post, text or email) to fill in a questionnaire to ask about your shoulder and general health, which will be similar to the previous questionnaires but without the assessment of strength or movement.

Which treatments are you comparing?

- ***Arthroscopic debridement***

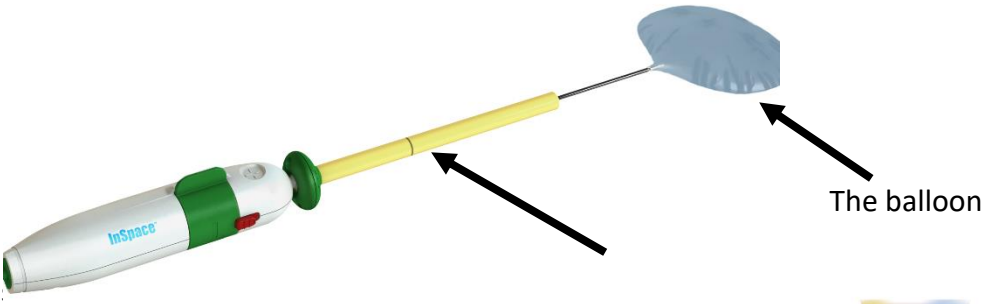
This is a keyhole operation involving two or three small incisions (approximately 1cm) around the shoulder. The surgeon looks around the main shoulder joint, they will take away loose or inflamed tissue, and shave some of the bone to create space to allow more movement and reduce pain. The surgeon may also choose to cut the end of the biceps tendon, which can help with pain. It is a low risk operation and most people are able to go home the same day. The recovery from this procedure takes between six weeks and three months.



Picture: an arthroscopic debridement operation

- ***Arthroscopic Debridement with InSpace balloon***

This is the same operation as an arthroscopic debridement, but at the end of the procedure, the InSpace balloon is inserted. The balloon is made of a biodegradable material. It takes only a few minutes to insert.



Some hospitals perform this procedure routinely and some do not. If you do not enter this study, you may not be able to have the balloon, depending on the normal practice of your local hospital.

What are the possible disadvantages and risks of taking part?

There are general risks with any shoulder operation, such as infection, stiffness, frozen shoulder (a very stiff shoulder, which recovers), worsened pain, blood clots, wound healing problems or anaesthetic problems (including death). These risks are all small and are from the operation that everyone in this study has.

The additional risk from taking part in the study is also small. The shoulder balloon can be put in the wrong place, or move after the operation and occasionally may have to be surgically removed, or can cause inflammation in the shoulder. These problems are uncommon and have occurred in less than 5% (1 in 20) of people who have had the balloon so far.

Between 8 weeks and 12 weeks after the operation you may have some discomfort in your shoulder, this is mild and normally resolves within 2 weeks.

To put the balloon in, one of the wounds needs to be half a centimetre wider than the others (approximately 1.5cm). So you cannot tell which treatment you have had, the skin wounds will be the same in both groups in this study. This will have no harmful effect, the risk is the same as the normal operation, and this will not affect your recovery.

What are the possible benefits of taking part?

There are no specific benefits to taking part. Both treatments are designed to help your shoulder recover. By taking part in the trial you are helping to decide about the best treatment for people in the future.

What if new information becomes available?

Sometimes during the course of a study, new information becomes available about the treatments that are being studied. If this happens, someone will tell you about it and discuss with you whether you want to continue in the study. If you decide to withdraw, you can discuss your continued care with your doctor. If you decide to continue in the study you might be asked to sign an updated consent form.

What happens when the research study ends?

You will be in the study for 24 months. If you are having any problems relating to the shoulder after this time, your general practitioner can arrange for you to see your specialist to continue your care.

When we have enough people who have had the operation to answer

the question, we will stop entering new people into the study. If you have consented but the study ends before you have had your operation, your surgeon will decide what operation is best and offer that to you

Will my taking part in this study be kept confidential?

The University of Warwick and the University Hospital Coventry and Warwickshire are the sponsors for this study based in the United Kingdom. The University of Warwick will act as the data controller and will be using information from you and your medical records in order to undertake this study. This means that the University of Warwick are responsible for looking after your information and using it properly. The University of Warwick will keep identifiable information about you for a minimum of 10 years after the study has finished.

Your rights to access, change or move your information are limited, as we need to manage your information in specific ways in order for the research to be reliable and accurate. If you withdraw from the study, we will keep the information about you that we have already obtained. To safeguard your rights, we will use the minimum personally-identifiable information possible.

Please follow the link below to find out how the University of Warwick handle your personal data processed in connection with the study:

https://warwick.ac.uk/services/idc/dataprotection/privacynotices/researchprivacynotice

Relevant information from you and your medical records (e.g. medical history and images) will be collected by your NHS site for this research study in accordance with our instructions. Your NHS site will use your name, NHS number, hospital number and contact details to contact you about the research study, and make sure that relevant information about the study is recorded for your care, and to oversee the quality of the study

The information collected from you and your medical records, by your NHS site, will be securely passed to the University of Warwick. The only people in the University of Warwick who will have access to information that identifies you (name, NHS number, hospital number and contact details) will be people who need to contact you to remind you to complete study questionnaires, to follow-up with you about any missing information or to audit the data collection process. Your NHS number may be used for linking with other NHS datasets to find out what has happened to your shoulder in the future. The people who analyse this information will not be able to identify you and will not be able to find out your name or contact details.

Individuals from The University of Warwick and the University Hospital Coventry and Warwickshire and regulatory organisations may look at

your medical and research records to check the accuracy of the research study.

When you agree to take part in a research study, confidential information (which does not identify you in any way) about your health and care may be provided to researchers running other research studies in this organisation and in other organisations. These organisations may be universities, NHS organisations or companies involved in health and care research in this country or abroad. Your information will only be used by organisations and researchers to conduct research in accordance with the UK Policy Framework for Health and Social Care Research. This information will not identify you and will not be combined with other information in a way that could identify you. The information will only be used for the purpose of health and care research, and cannot be used to contact you or to affect your care. It will not be used to make decisions about future services available to you, such as insurance.

Your NHS site will keep identifiable information about you for this study for a minimum of 10 years after the study has finished.

Access to this data will be restricted to authorised personnel only.
All of your data will be handled with full data security measures and will not be shared outside of the study team.

If you agree to take part, your GP and other doctors who may treat you, but are not part of this study, may be notified that you are taking part in this study. If we are not able to keep in touch with you, we may contact your GP in the future to collect your health records so we know if you have had any problems related to the operation.

What happens if something goes wrong?

In the event that something goes wrong and you are harmed during the research due to someone's negligence, then you may have grounds for legal action for compensation against the University of Warwick (contact the Head of Research Governance, Impact Services, University House, University of Warwick, Coventry, CV4 8UW or by email researchgovernance@warwick.ac.uk or telephone 02476 522746)

Who should I contact if I wish to make a complaint?

Any complaint about the way you have been dealt with during the study or any possible harm you might have suffered will be addressed. Please address your complaint to the person below, who is a Senior University of Warwick Official, entirely independent of this study:

Deputy Director/Head of Research Governance
Research and Impact Services
University House
University of Warwick

Coventry, CV4 8UW
Tel: 02476 522746 Email: researchgovernance@warwick.ac.uk

For independent advice contact the PALS service (Patient Advice Liaison Service) on <<local PALS phone number>> or follow the NHS complaints procedure.

What will happen to the results of the research study?

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 contact the study manager on 02476968629 or START@warwick.ac.uk

Who has reviewed this study?

This study has been reviewed and approved by the West Midlands – Coventry & Warwickshire Research Ethics Committee and the Health Research Authority. It has been reviewed by numerous experts throughout the United Kingdom and by the National Institute of Health Research (NIHR). It has also been reviewed by an independent steering committee who oversee this study.

Who is organising and funding the research?

This research has been organised by the University of Warwick and the University Hospitals Coventry and Warwickshire. It has been funded by the UK NHS research body, the National Institute for Health Research, though its Efficacy and Mechanism Evaluation Programme.

Contacts for further information

If, at any time, you would like further information about this research project you may contact your local Research Team on *<<local research contact details>>* or email START@warwick.ac.uk

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