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PATIENT INFORMATION SHEET

Partial Rotator Cuff Tear Repair Trial (PRoCuRe)

You are being invited to take part in a research study called PRoCuRe.

Before you decide if you want to take part, it is important for you to know why this research is being done and what it would involve for you.

Please take some time to read this information about the PRoCuRe study, and talk it through with others (friends, family, your GP) if you wish. If anything is unclear, you would like more information, or you have any concerns, please do not hesitate to ask a member of your local PRoCuRe team. Their contact details can be found at the end of this information sheet.

1. What is the purpose of the PRoCuRe Study?

Even though rotator cuff problems are the most common cause of shoulder pain and disability, we do not know how *best* to treat some of these problems. For people with shoulder pain and partial thickness rotator cuff tears, we don't know if keyhole surgical repair of these tears is the best option, or whether it provides lasting benefit and prevents bigger full tears in the future. This study aims to find the answers to these questions, as well as recording the costs of the treatments, and any future treatment(s).

2. Why have I been invited to take part in PRoCuRe?

You are being invited because you have persistent shoulder pain that has not resolved after 6 months of physiotherapy exercises and a steroid injection, and you have decided with your surgical team to have surgery on your shoulder. Your shoulder scan also suggests that you may have a type of rotator cuff tendon tear called a partial thickness tear. This means your surgical team has identified you as someone who meets the entry criteria and would be happy for you to enter the study, should you wish to take this opportunity to participate in a national research study. If you are interested in taking part, your hospital team will further assess your eligibility against the full list of criteria as described in the study protocol; if you wish you can find this full list of inclusion and exclusion criteria on our webpage: https://procure.octru.ox.ac.uk/

3. Do I have to take part?

No, taking part in research is always optional. If you do not take part, this will not affect the care that you receive. If you decide to take part, you will be asked to sign a consent form to document your agreement to participate. You are free to leave the study at any point without giving a reason and, again, this will not affect your care.

4. What will happen if I decide to take part?

During your outpatient appointment: If you have decided to have surgery and your surgeon thinks that the PRoCuRe study could be a good option for you, they will discuss the study with you (they may also ask you to consent to having this discussion audio-recorded for training purposes; see section 4.1 on page 4). If you are willing to consider the study, they will further assess whether you are eligible to take part by looking at your hospital record.

If you meet the initial eligibility requirements for the PRoCuRe study, you will be given verbal and written information to explain the study, and what taking part would mean for you. Your local research team will contact you a few days later to talk about the study and answer any questions you may have. If you have decided to take part, a member of the local PRoCuRe research team will organise to meet you at your next hospital appointment where they will ask you to read and sign a consent form. After providing your consent, you will be asked to fill out a questionnaire about your shoulder (you may be asked to repeat this questionnaire if your surgery is delayed, but your clinical team will let you know if this is the case).

During your operation: Your surgeon will use a keyhole camera to check and confirm that you have no other problems except for a partial thickness tear of the rotator cuff. If this is the case you become eligible for randomisation to receive a PRoCuRe treatment.

- If you ARE eligible

  Your surgeon will perform one of two PRoCuRe procedures, either:

  Arthroscopic Debridement WITHOUT Repair*

  or

  Arthroscopic Debridement WITH Repair*

**Descriptions of both operations can be found at the end of this information sheet (section 21.).*

- If you are NOT eligible

  Your surgeon will provide routine surgical treatment for your shoulder problem as identified during surgery.

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If you are eligible for randomisation and have consented to provide the small sample of your tendon tissue that is usually removed or shaved away during surgical treatment, this will be collected and packaged during your operation (see section 4.2 on page 4).

Whether you are eligible for randomisation or not, we will ask your surgeon to provide us with information on your operation.

After surgery: You will be given a post-operative rehabilitation booklet to follow and your surgical and physiotherapy team will also follow you up as per your local hospital guidelines. The booklet will have useful instructions on your recovery, sling wearing and mobilising and exercising your arm.

Following your treatment:

If you were eligible for randomisation

We will send you a questionnaire to fill out at four timepoints after your operation (6, 12 and 24 months, and then 5 years after surgery). You can choose to receive and complete this questionnaire online (by email) or on paper (by post). You will not need to return to hospital to complete your questionnaires as they can be done at home. A copy of your completed questionnaire will be shared with your local hospital PRoCuRe research team so that they have a record of your participation.

Each questionnaire will take around 10 minutes to complete. If we do not receive your questionnaire back within ten days, we will contact you again using other methods of communication, including by telephone, to remind you.

We will also ask you to attend an MRI scan of your shoulder 24 months after surgery. Your local hospital research team will arrange this for you. Your scan will be anonymised and then sent to the PRoCuRe study management team in Oxford where it will be independently reviewed. Please note: This scan is for research purposes only and results will not routinely be fed back to you or your surgeon. However, if the radiologist happens to notice an abnormality that they think might be potentially serious, we will contact you and your GP.

5 years after your surgery, in addition to sending you a questionnaire, we will request routine information on you that is held by NHS Digital on the Hospital Episodes Statistics (HES) database. This is so we can find out (without disturbing you 5 years later with lots of questionnaires) about any further treatment or problems you might have had with your shoulder. If you consent to take part in PRoCuRe, we will ask you to give your permission for us to do this, we will then not need to contact you again to access this information.

If you were not eligible for randomisation

5 years after your surgery, we will request routine information on you that is held by NHS Digital on the Hospital Episodes Statistics (HES) database. This is so we can find out (without disturbing you 5 years later with questionnaires) about any further treatment or problems you might have had with your shoulder. If you consent to take part in PRoCuRe, we will ask you to give your permission for us to do this, we will then not need to contact you again to access this information. We will not send you any follow-up questionnaires to complete and you will not be asked to attend an MRI 24 months after surgery.

4.1 PRoCuRE Information Study

To help us ensure we present information as clearly as possible to patients like you, we would like to invite you take part in a related 'Information Study'. Your research team will go through the separate 'Information Study' leaflet and consent form with you to further explain this. In short:

a) We would like to audio-record the discussions your surgeon and any members of the research team have with you about taking part in the PRoCuRe study.

b) We would like some patients to take part in a short telephone interview (approx. 20 mins) about the reasons why they chose to take part, or decline, the PRoCuRe study.

Please note: You can choose NOT to take part in the Information Study and STILL take part in the PRoCuRe study. Likewise, you can decline the PRoCuRe study, and still take part in the Information Study.

4.2 Tissue Sample

Often, there is a small amount of tendon tissue (around the size of a grain of rice) that is routinely removed and discarded during surgery. You may be invited to consent to allow this tissue to be collected for laboratory analysis at the University of Oxford. The tissue samples will help to identify possible future prevention and treatments for people with rotator cuff tears.

The tissue sample will be de-identified and labelled only with your unique PRoCuRe study number. Your sample will then be packaged and sent by approved courier to the University of Oxford. Researchers conducting the tests will not receive any of your personal identifiable information and you will not be identifiable in any published results. At the end of the PRoCuRe study, if you agree, any tissue that has not been used up will be kept in the Oxford Musculoskeletal Biobank (OMB) and used on future related and approved studies.

Your de-identified sample stored at the OMB will be used mainly by local researchers, but ethically approved research projects may take place in hospitals, universities, non-profit institutions or commercial laboratories worldwide.

You are free to request that any unused tissue sample is destroyed at any time during or after the study.

Please note: You can choose NOT to provide a tissue sample and STILL take part in the PRoCuRe study.

5. If I am eligible, which PRoCuRe procedure will I undergo?

To make sure that the results of the study are fair, the treatment is decided at random by a computer programme. This means everyone who takes part in the study will be in one of two groups. Because the computer decides at random, it means both groups of people in the study are the same to start with, and neither you nor the study team will know which group you will be in. Your surgical team will be aware of your allocation and we will also notify your GP to which treatment you receive. One group will receive Arthroscopic Debridement WITHOUT Repair, one group will receive Arthroscopic Debridement WITH Repair. Whichever group you are put into, the care you will receive is considered part of standard routine care that takes place all over the NHS, and every other aspect of your care will be the same.

Dividing people into groups in this way is what makes the research a 'randomised controlled trial' (RCT). RCTs are the most reliable way of assessing how good a treatment is.

6. If I have a PRoCuRe procedure, will I know which one I had?

No. PRoCuRe is a blinded RCT. You will not know which type of surgery you had. This will allow us to compare the two procedures as fairly as possible.

If you become unblinded at any time, please tell us. It will not affect your participation the study or your care, but it will allow us to take this into account when analysing the results.

7. If I have a PRoCuRe procedure, when can I find out which one I had?

You will be able to find out the day after the last patient in the study completes their 5-year follow-up assessment. This delay is necessary to prevent any unfairness within the study. If it is deemed clinically necessary to inform you before this time, your surgeon will do so.

8. Are there any risks or disadvantages to taking part?

Outside of the usual risks associated with surgery and anaesthetic, there are no anticipated risks or disadvantages to participating in the PRoCuRe study. Taking part in the study will not change the standard of care you receive. Whichever type of treatment you receive, your care will be coordinated by your local specialist shoulder surgeon. Your surgeon will be able to tell you about the risks and complication rates of surgery in your own hospital, and describe the steps that are taken to minimise these.

Both PRoCuRe procedures are already performed routinely in the NHS and there is no expected difference in the risk between them.

MRI is safe and non-invasive and does not involve any radiation like x-rays. However, because they use a large magnet to work, MRI scans are not suitable for a small number of people.

Because of this, the PRoCuRe participant eligibility check involves establishing whether an MRI scan would be appropriate for you.

Before you have your MRI scan your local hospital team will do further safety checks to ensure this type of scan is suitable for you. For example: if you have claustrophobia an MRI scan may not be appropriate for you; other reasons may include having a pacemaker, a hip replacement, or other non-removable pieces of metal within your body. To make sure there's no metal in your clothing your hospital team may give you 'pyjama-style' top and trousers to wear during the scan. Scans can be noisy so you may also be given earplugs or headphones to wear. Your local hospital team will provide you with full details of the procedures for MRI at your hospital, they will also answer any questions or concerns you have.

9. What are the possible benefits of taking part?

We cannot guarantee a benefit to participants. This study is trying to find out which of the two surgical treatments we are comparing might be best, but until we've finished the study, we can't be sure which one might be better, or whether they are the same.

The main benefit from your taking part in the study will be the information you provide which may help to improve treatment in the future. The results of the PRoCuRe study are likely to benefit future NHS patients with shoulder complaints like yours.

10. Who will know that I am taking part in the study?

Your details will be sent to the central research team in Oxford so that they can organise sending you postal or online questionnaires and we will let your GP know that you are taking part in the study.

11. Will my taking part in this study be kept confidential?

Yes, you will be allocated a study number and all patient information will be stored securely in accordance with data protection rules. Access to this information will be monitored and restricted to staff who require it to undertake their role. At the end of the study, data will be de-identified so people who have taken part will not be identified.

Responsible members of the University of Oxford, regulatory authorities or your NHS trust, may be given access to data for monitoring and/or audit purposes of the study to ensure the research is complying with regulations.

12. What will happen to my data?

Data protection regulation requires that we state the legal basis for processing information about you. In the case of research, this is 'a task in the public interest.' The University of Oxford is the data controller and is responsible for looking after your information and using it properly.

We will be using information from you and your medical records and NHS Digital (HES database) and other central NHS registries in order to undertake this study. We will use the minimum personally-identifiable information possible. In order to collect information about your longer-term complications, the study team will send identifying patient information (name, NHS number, gender, date of birth and postcode) to NHS Digital. This will allow NHS digital to link your identifying details to the hospital episode data and send back data relating your shoulder. The data that is sent back will not contain any identifying information though PRoCuRe researchers at University of Oxford could link it to your personal records using a study specific ID number, if required.

We will keep identifiable information about you for up to 12 months after the study has finished. Your medical data will be held separately from your personal details and will be linked to you through your study ID number. This excludes any research documents with personal information, such as consent forms, which will be held securely at the University of Oxford for at least 5 years after the end of the study. If you agree to your unused samples being used in future research, your consent form will be held until the samples have been depleted or destroyed, or 5 years, whichever is longer.

Your local hospital PRoCuRe team will use your name, and contact details to contact you about the research study, including, where applicable, organising the MRI scan 24 months after surgery. They will keep identifiable information about you from this study for up to 12 months after the study has finished. This excludes any research documents with personal information, such as consent forms, which will be archived at the NHS Hospital Trust site as per local Trust policy for medical notes retention for at least 5 years after the end of the study. Data protection regulation provides you with control over your personal data and how it is used. When you agree to your information being used in research, however, some of those rights may be limited in order for the research to be reliable and accurate.

Further information about your rights with respect to your personal data is available at https://compliance.web.ox.ac.uk/individual-rights

You can find out more about how we use your information by contacting procure@ndorms.ox.ac.uk or going to procure.octru.ox.ac.uk

13. What happens when the study finishes?

The results of the study will be published in a medical journal. The results will also be available on the study website.

You will not be identified from any report or publication placed in the public domain.

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

Taking part in PRoCuRe is voluntary; if you decide to withdraw from the study you can do so at any time. You do not need to give a reason for your decision, and it will not affect your hospital care. You can request that any information that you have provided up to the point you withdraw is not used in the final study analysis. Please note that there are limits to this; for example, when the data has already been included in interim analysis or we can no longer identify the data as yours.

If you change your mind and wish to leave the study you please contact your local study team.

<<Insert Local Contact Details>>

15. Who is organising and funding this research?

The study is sponsored by the University of Oxford. The Surgical Intervention Trials Unit (SITU) at Oxford will manage the study with Oxford Clinical Trials and Research Unit (OCTRU). The National Institute for Health Research, Health Technology Assessment programme, has funded the study. Activities specific to the collection of tissue samples are funded through the National Institute for Health Research Oxford Biomedical Research Centre, Musculoskeletal Theme.

16. Who has reviewed this study?

All research in the NHS is looked at by an independent group of people, called a Research Ethics Committee, to protect participants' interests. This study has been reviewed and given favourable opinion by London - Central Research Ethics Committee.

17. Expenses and Payments

There is no payment to people taking part on the PRoCuRe study but reasonable travel expenses to the hospital for the MRI scan 2 years after surgery can be reimbursed. Ask your local research team for further details on this.

If you receive your study questionnaires in paper format, a free post return envelope will be provided.

18. What if there's a problem during the study?

The University of Oxford, as Sponsor, has appropriate insurance in place in the unlikely event that you suffer any harm as a direct consequence of your participation in this study. NHS indemnity operate in respect of the clinical treatment which is provided. Taking part in the study will not affect your legal rights.

If you wish to complain about any aspect of the way in which you have been approached or treated during the course of this study, you should contact your local Principal Investigator.

<insert name and contact details>

or

The PRoCuRe management office, Oxford
procure@ndorms.ox.ac.uk or by telephone (01865) 227684

or

The University of Oxford Clinical Trials and Research Governance (CTRG) office at:
ctrg@admin.ox.ac.uk or Telephone: 01865 616480

19. What if I am concerned about my clinical care?

The Patient Advisory Liaison Services (PALS) is a confidential NHS service that can support you with any complaints and questions you might have about your care at your local NHS hospital. Please note that PALS is unable to provide specific information about this research study. If you wish to contact your local PALS teams, please contact:

Email: <insert PALS email address>

Telephone: <insert PALS telephone number>

20. How have patients and the public been involved in this study?

In designing this study, we have taken into account patient opinions on aspects such as the number and frequency of questionnaires. They have also provided review and comment of this information sheet and other study documents. Patients will continue to be involved in the delivery and oversight throughout this study. For general information about taking part in research visit: www.nihr.ac.uk/patients-carers-and-the-public/i-want-to-help-with-research/

21. Description of both PRoCuRe Surgical Procedures

	Arthroscopic (keyhole) Debridement WITHOUT Repair	Arthroscopic (keyhole) Debridement WITH Repair
Type of surgery	Keyhole surgery	Keyhole surgery
Type of Anaesthetic	Usually general anaesthetic	Usually general anaesthetic
Usual duration of Surgery	30 mins	60 mins
Description of surgery	2-3 keyholes are made around the shoulder, the shoulder is fully examined from inside. If no other problems are found other than a partial thickness tear of the rotator cuff tendon, then the surgeon will clear inflamed tissue from around the tendon (called the bursa) and shave the tendon edges if they are ragged. The surgeon may also shave away a bone spur from above the tendon tear if one is present.	2-3 keyholes are made around the shoulder, the shoulder is fully examined from inside. If no other problems are found other than a partial thickness tear of the rotator cuff tendon, then the surgeon will clear inflamed tissue from around the tendon (called the bursa) and shave the tendon edges if they are ragged. The surgeon may also shave away a bone spurs above the tendon tear if one is present. The surgeon will then do an extra step of trying to fully repair the tendon tear by placing a small anchor (like a small screw) into the bone. The anchor has some stitches that can be passed around the tendon tear to hold it to the bone to encourage healing.
Who does the procedure?	A specialist orthopaedic shoulder surgeon	A specialist orthopaedic shoulder surgeon
Time in hospital after	Usually day case	Usually day case
Complications/side effects	No difference expected between the 2 procedures. Your surgeon will always discuss any potential complications when you sign your consent form for surgery.	No difference expected between the 2 procedures Your surgeon will always discuss any potential complications when you sign your consent form for surgery.

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Thank you for taking the time to read this information sheet and for your interest in the PRoCuRe study.

Contact your local PRoCuRe Team:

<<Insert Local Contact Details>>

Please use this section to make notes and write down any questions you have about PRoCuRe:

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