Operative versus Non-Operative Treatment for Atraumatic Rotator Cuff Tears: A Multicenter Randomized Controlled Pragmatic Trial

NCT03295994

Date of IRB Approval: July 26, 2023

Study Title: **Operative versus Non-Operative Treatment for Atraumatic Rotator Cuff Tears: A Multicenter Randomized Controlled Pragmatic Trial**
Version Date: **March 19, 2021 (v6.0)**

Part 1 of 2: MASTER CONSENT

Name of participant: _____ Age: _____

The following is given to you to tell you about this research study. Please read this form with care and ask any questions you may have about this study. Your questions will be answered. Also, you will be given a copy of this consent form to keep.

You are being invited to take part in a research study. This study is a multi-site study, meaning it will take place at several different locations. Because this is a multi-site study this consent form includes two parts. Part 1 of this consent form is the Master Consent and includes information that applies to all study sites. Part 2 of the consent form is the Study Site Information and includes information specific to the study site where you are being asked to enroll. Both parts together are the legal consent form and must be provided to you.

Key Information:
The first section of this document contains some key points that the research team thought you would find important. The study is described in more detail after this section. If you do not understand something, please ask someone.

This informed consent applies to adults with rotator cuff tears.

What is the purpose of this study?

You are being invited to take part in this research study because we want to find the best way to treat rotator cuff tears in people ages 40-84. The rotator cuff is a group of 4 tendons that help to move the shoulder. A tear in one or more of these 4 tendons can result in shoulder pain and reduced shoulder movement. Rotator cuff tears can be treated either with surgery or with physical therapy alone. Both of these are standard treatments prescribed by doctors for people with rotator cuff tears, and both have worked for some people. However, we do not know which of these works best and for whom.

What will happen and how long will you be in the study?

For this study participants must have an MRI-confirmed rotator cuff tear. We will use the MRI ordered by your doctor as part of your clinical evaluation to see if you qualify for this study.

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If you qualify for this study and agree to take part, you will be randomly assigned by a computer to one of two treatment groups for your rotator cuff tear:

- Operative Treatment (surgery + physical therapy), or
- Non-Operative Treatment (physical therapy without surgery)

This means that neither you nor your doctor will decide which treatment option you receive. Therefore, if you participate in the study, you must be willing to NOT CHOOSE your own treatment. You will only be enrolled in this study if your doctor thinks either of the two treatment options could help you.

Your participation in this study may last up to 10 years, from initial enrollment to final follow up. For the most part, this will involve completing follow up questionnaires by mail or online. Here's what will be involved if you choose to participate:

At initial enrollment (this will take approximately 1-2 hours);
*Note: These procedures may be performed in clinic and/or remotely as appropriate

- Learn about the study and sign the consent form, if you wish to participate
- Complete a questionnaire about your personal medical history, symptoms, and shoulder function
- Complete an authorization form to allow us to receive information from your treating physical therapist(s)
- Have a brief physical exam to measure your shoulder strength and range of motion
- Be randomly assigned to a treatment group
    - Those assigned to the **Operative treatment** group will have surgery to repair their rotator cuff tear, followed by approximately 4 months of physical therapy to help restore strength and movement.
    - Those assigned to the **Non-Operative treatment** group will have approximately 3 months of physical therapy (without surgery) to restore shoulder function by strengthening and stabilizing the supporting muscles.

The treatment of your rotator cuff tear may require additional visits as determined by your doctor. These will be based on what is customary or necessary depending on your course of treatment and your individual treatment needs. There will be no additional treatment-related visits required as part of this study beyond those you would otherwise make for standard operative or non-operative treatment of your shoulder.

3, 6, & 12 months after treatment
- Complete a follow-up questionnaire on paper or electronically (tablet or computer)
- Return a completed physical therapy diary (as applicable)

Each year thereafter (for up to 10 years)
- Complete a follow-up questionnaire on paper or electronically (tablet or computer)

On one occasion after treatment (approximately 2-10 years after treatment)
- Potentially return to clinic for a follow-up physical exam (at no cost to you)
- Potentially have a follow-up MRI for research purposes (the study would pay for this)

Schedule of Study Procedures:

Procedures	Enrollment	3 Month Follow Up	6 Month Follow Up	12 Month Follow Up	2 Year Follow Up	3 Year Follow Up	4 Year Follow Up	5 Year Follow Up	6 Year Follow Up	7 Year Follow Up	8 Year Follow Up	9 Year Follow Up	10 Year Follow Up	Follow Up Visit (2-10 yrs after treatment)
Physical Exam	X*													X*
Questionnaire	X	X	X	X	X	X	X	X	X	X	X	X	X	
PT Diary		X	X	X*										
Research MRI														X*

* If applicable

Description of Procedures:

Physical Therapy Diary (PT Diary): While receiving physical therapy for your shoulder, you will complete a simple daily diary to record what you did each day for your physical therapy program. You can choose whether to keep your diary on paper or electronically, using a special

smartphone app called MyCap. You will only complete the PT diary while you are actively attending physical therapy.

Physical Exam: The physical exam will take about 10 minutes. Strength and range of motion measurements will be taken for both shoulders. Shoulder strength is measured using a handheld device that you will be asked to push against. Shoulder range of motion is measured by raising each arm in several positions and recording the result on a diagram. (If range of motion measurements are taken as part of your clinical visit, these may be used in lieu of a separate exam.) NOTE: There may be instances where one or both parts of the physical exam will not be administered due to clinic policies or the mode of the clinic visit (e.g., telehealth).

MRI: The MRI scan will take about 60 minutes. An MRI scan is taken in a large machine that is shaped like a tunnel. This scan does not use x-rays. Instead, it uses use a strong magnet and radio waves, like those used in an AM/FM radio to make pictures of your body.

You may not be able to have this scan if you have a device in your body such as aneurysm clips in the brain, heart pacemakers or defibrillators, and cochlear implants. Also, you may not be able to have this scan if you have iron-based tattoos or pieces of metal (bullet, BB, shrapnel) close to or in an important organ (such as the eye).

Certain metal objects like watches, credit cards, hairpins, writing pens, etc. may be damaged by the machine or may be pulled away from the body when you are getting the scan. Also, metal can sometimes cause poor pictures if it is close to the part of the body being scanned. For these reasons, you will be asked to remove these objects before going into the room for the scan.

You will hear “hammering”, clicking, or squealing noises during the scan. You will be given earplugs to reduce the noise. You will also be told how to alert the staff if you need them. During the scan, the MRI staff is able to hear and talk to you. You will also be able to hear the staff. They will be talking to you during your scan and may ask you to hold your breath, not move, or other simple tasks. You may be asked to lie very still throughout the scan.

Both your initial clinical MRI (before beginning the study) and your follow -p research MRI will be reviewed by an independent radiologist to verify the results. This review is for research purposes only. But, if we see something that is not normal, you will be notified and asked to consult your doctor.

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Detailed Information:
The rest of this document includes detailed information about this study (in addition to the information listed above).

YOUR PARTICIPATION IS VOLUNTARY: You do not have to take part in this research study. Whether or not you participate is entirely up to you. You may choose not to be in this study and get other treatments without changing your healthcare, services or other rights. If you do decide to participate in the study, you may withdraw from the study at any time. Your medical record will contain a note saying you are in a research study. Anyone you authorize to receive your medical record will also get this note.

Side effects and risks that you can expect if you take part in this study:

Potential physical risks include:

- fatigue due to answering study questionnaires
- pain and discomfort during the physical exam

The medical risks of participating in this study depend on which treatment you are assigned to.

- For **physical therapy**, the risks include increased pain or no improvement of pain and function.
- For **surgery**, the risks include those commonly associated with surgery, such as: post-operative bleeding or infection, blood clot, hospital readmission, complications related to anesthesia, and, in rare cases, death. Other risks for surgical treatment of rotator cuff tear include: nerve injury, adhesive capsulitis (frozen shoulder), and no improvement of pain & function. Surgery also involves recovery time following the operation. Your arm may be in a sling for up to 6 weeks. Daily activities such as driving, lifting objects, and exercising may be restricted for up to 3 months.

MRI Risks: There are no known major risks with an MRI scan. But, it is possible that harmful effects could be found out in the future. Even though the tunnel is open, it may bother you to be placed in a tight space (claustrophobia), and to hear the noise made by the magnet during the scan. You will be given earplugs to reduce the noise. You may also feel the table vibrate and/or move slightly during the scan. It may be hard to lie on the table during the scan. If you have any metal pieces in your body, they could move during the scan and damage nearby tissues or organs.

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If you use a transdermal patch (medicated patches applied to the skin), you may need to take it off during the MRI scan. Transdermal patches slowly deliver medicines through the skin. Some patches have metal in the layer of the patch that is not in contact with the skin (the backing). You may not be able to see the metal in the backing of these patches. Patches that contain metal can overheat during an MRI scan and cause skin burns in the immediate area of the patch. Tell the study doctor that you are using a patch and why you are using it (such as, for pain, smoking cessation, hormones). Ask your doctor for guidance about removing and disposing of the patch before having an MRI scan and replacing it after the procedure. Tell the MRI facility that you are using a patch. You should do this when making your appointment and during the health history questions you are asked when you arrive for your appointment.

This MRI scan does not involve use of a contrast agent (dye). There are no known risks of having MRI scans without contrast while pregnant. However, there may be risks that are unknown.

The MRI used in this study has been used in human research for several years and no risks have been identified. However, some people may experience discomforts such as nausea, dizziness, flashing lights in the eyes, and a metal taste in the mouth. These discomforts are most likely to occur as a result of rapid head movement in or near the MRI machine. For this reason, you should try not to move, especially your head, while you are inside the MRI.

Risks that are not known:

In addition to the possible risks listed above, there may be risks and side effects that are currently unknown and/or unexpected. We will tell you if we learn any new information about risks that may affect your willingness to stay in this study.

Good effects that might result from this study:

a) **The benefits to science and humankind that <u>might</u> result from this study**. The information from this study may improve understanding and treatment of rotator cuff tears for patients in the future.
b) **The benefits you might get from being in this study.** There is no direct benefit to you for participating in this study.

Other treatments you could get if you decide not to be in this study:

Your alternative is to not participate in this study and not have a treatment assigned to you. If you choose not to participate, you may choose your own treatment in consultation with your doctor just as you normally would.

Payments for your time spent taking part in this study or expenses:

You will be compensated for your time and inconvenience in filling out the study questionnaires and for returning in person for a follow up visit and MRI.

- $100 for the initial questionnaire and physical exam at enrollment
- $50 for each completed follow-up questionnaire you return (up to 12 questionnaires total)
- $100 for the time involved in returning for your one-time, research follow-up visit & MRI approximately 2-10 years after treatment of your shoulder.

If you complete all of the questionnaires & return for the follow-up visit & MRI, you will receive up to $250 in the first year and up to $800 total over the course of the study.

This is a multi-site, national clinical trial, and patient payments will come from a coordinating center that may not be the site at which you were enrolled. For compensation of study procedures, you will be issued a UT Southwestern Greenphire ClinCard, which can be used as a credit or debit card. Compensation will be credited to the card after completion of each study procedure (listed above). This is a reloadable payment card. Keep the card safe once you receive it. All future payments will be loaded on this card. (You will not receive a new card for each payment.).

Your name, address, date of birth and social security number will be shared with a third-party solely for the purposes of compensation processing. All information will be stored in a secure fashion. If you choose not to provide a social security number, the payment will have 24% deducted from it for tax purposes (for example, Instead of receiving $100 for the initial questionnaire and physical exam, you will receive $76).

Please note that if you are on record as owing money to the State of Texas, such as for back child support or a delinquent student loan, the payment may be applied to that debt. An IRS Form 1099 will be sent to you if your total payments are $600 or more in a calendar year, unless it's a reimbursement.

Reasons why the study doctor may take you out of this study:

It is possible that we will have to ask you to drop out before you finish the study. Reasons for this may include:

- Any serious adverse event (SAE) or other medical condition or situation occurs such that you cannot continue or continued participation in the study would not be in your best interest
- If you don't return any follow-up questionnaires in the first year
- If you don't return yearly follow-up questionnaires two years in a row
- If the study ends earlier than anticipated

If this happens, you will be notified that you are no longer part of the study. Your care will not be affected by whether you continue in the study or not.

If it is determined that you meet an exclusion criterion after enrollment and randomization, have a delay in treatment or do not receive your assigned treatment you will not be withdrawn from the study. We will still follow up with you via questionnaires as planned.

What will happen if you decide to stop being in this study?

If you decide to stop being part of the study, you should contact the ARC Trial Coordinator at your study site. (See study site contact info at beginning of Part 2: Study Site Information.) Deciding to stop being part of the study will not change your regular medical care in any way.

Clinical Trials Registry:

A description of this clinical trial will be available on www.clinicaltrials.gov, as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.

Confidentiality:

Your confidentiality is held in strict trust by the study doctors, study staff, study funders/sponsors and their agents. To protect your privacy, you will be assigned a unique study ID number. Whenever possible your study ID will be used instead of your name or other identifying information on forms and in communication between study personnel.

In this study, we may collect health information about you from:

- Past, present, and future medical records
- Research procedures, including research office visits, physical exams, tests (including MRIs), interviews, and questionnaires
- Treatment providers, including your surgeon and your physical therapist(s), about study-related operative & non-operative treatments

Your paper research records will be stored in a locked file cabinet. Electronic data, including scanned copies of any paper forms, will be stored in a password-protected REDCap computer database. This is a special research database stored on a secure server. Only authorized study personnel from any of the participating study sites (past, present, or future) will have access to this database and your paper research records. The REDCap system automatically tracks all access to and actions performed in this computer database so they can be easily monitored.

The study monitor(s), auditor(s), the IRB/IEC, and the regulatory authority(ies) will be granted direct access to your original medical records for verification of clinical trial procedures and/or data, without violating your confidentiality, to the extent permitted by the applicable laws and regulations. By signing a written informed consent form, you are authorizing such access.

The study funder, Patient-Centered Outcomes Research Institute (PCORI), or any future study funder/sponsor, the data and coordinating center(s) for this study, and/or your study site may share your information, without identifiers, to others or use it for other research projects not listed in this form. PCORI, the data and coordinating center(s) for this study, your study site, the site principal investigator and his/her staff will comply with any and all laws regarding the privacy of such information. There are no plans to pay you for the use or transfer of this de-identified information.

Newsletter Opt-In:

Would you like to stay informed about what's happening in the study and receive information about your shoulder? Please sign up for our patient newsletter by checking the box below. Checking the box below allows us to add your e-mail to our subscription list hosted by Constant Contact. You can opt-in or out at any time and we will not share your information outside of our study team and Constant Contact. Constant Contact will not share your email with any third-party vendors. The newsletter and an opt-in link will also be available on the study website, www.shoulderstudy.org.

☐ Yes, sign me up!

☐ No, not right now.