

This clinical trial will include 190 patients across several hospitals in Australia.

This study is conducted by researchers in musculoskeletal health and orthopaedics in Australia and led by Professor Ian Harris and is sponsored by The University of New South Wales.

Why have I been invited to participate

You have been invited to participate because you have been diagnosed with a reparable rotator cuff tear, have been suffering shoulder problems for at least the last six months and are aged between 45-75 years.

Participation in this study is entirely voluntary. It is completely up to you whether or not you participate.

If you agree to participate you are free to withdraw at any time and you can do so without giving a reason. Whatever your decision, it will not affect your relationship with your surgeon or the staff caring for you nor will it affect the treatment you receive now

or in the future at this hospital.



What will happen if I take part in the study

Before-surgery

You will be informed about the study in more detail and asked to sign a Participant Consent form or a video meeting can be organised where you can confirm you agree to participate.

You will also be asked to complete some questionnaires about your pain and mobility, quality of life and other aspects of your health.

Surgery

Everyone who participates in this trial will receive surgery called **arthroscopic surgery**. This surgery involves putting a camera and some small instruments into the shoulder through key holes.

You may have other procedures done such as cleaning out the soft tissues and any bone that might be causing problems, and surgery to other tendons (eg bicep tendon).

During surgery when it comes time to address the tear in the rotator cuff you will be **randomly allocated (50/50 chance) to one of either two study groups:** repair of your rotator cuff OR no repair of your rotator cuff.

After-surgery

Once the surgery is completed you will have your shoulder placed in a sling and you will be ***asked to undergo a physiotherapy program over several months***, just like people would normally get after rotator cuff surgery.

You will ***see a different shoulder specialist than your operating surgeon***. Your follow up with your surgeon will be as per usual including a repeat MRI scan one year later.

You will ***not be told which study group you belong to***. This is because when those involved in the research study are “blinded” to your study group, the answers to questions asked during the study will not be influenced by knowing which treatment was received.

You will be ***contacted by the study researchers who will ask you to complete questionnaires*** about your shoulder. Answering these questions will take no more than 30 minutes of your time.

Thank you for taking time to read this leaflet. If you are interested in taking part, please contact:

(local surgeon name and contact)



ARC

The Australian Rotator Cuff Trial

Is surgically repairing a rotator cuff tear better than not surgically repairing the tear, for people with shoulder problems?

Would you like to help answer this question?

If you would like more information, please leave your name and contact details below and hand this page in to your treating surgeon.

Full name: _____

Telephone number: _____

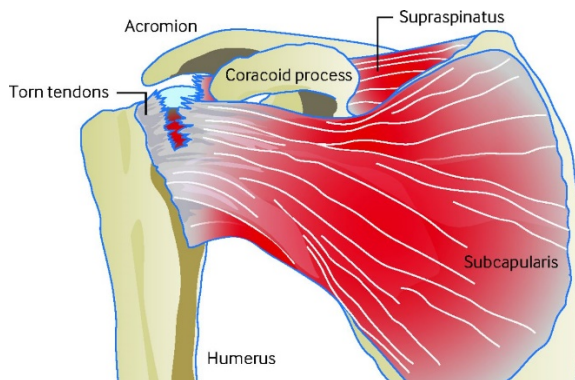
Email address: _____

By providing this information you consent that you are happy to be contacted by the ARC study member to contact you regarding your possible participation in the research trial.

What is a rotator cuff tear?

The rotator cuff is a flat tendon that sits inside the shoulder joint. It is the link between several muscles and the top of the arm bone.

The rotator cuff over time shows wear and splitting, often resulting in what is called a “degenerative tear”. These degenerative tears are very common and become more common with age.



If you have a rotator cuff tear and your symptoms (eg pain and weakness) cannot be relieved by non-surgical treatments such as physiotherapy, surgery may be offered.

The most common procedure is arthroscopic repair (stitching together) of the tear.

It is not clear whether surgical repair of rotator cuff tears in the shoulder leads to improvements in pain, function and quality of life when compared with not repairing the tear (no surgery).

The purpose of this study

Is surgical repair of a rotator cuff tear more effective in improving pain, function of the shoulder and quality of life compared with no surgical repair?

A high-quality scientific study is needed to answer this question.

This is a clinical trial that will compare arthroscopic shoulder surgery with the rotator cuff tear repaired to the same surgery but without repairing the rotator cuff
