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Comparing surgical and conservative treatments for rotator cuff tears

Submission date
19/01/2019

Recruitment status
No longer recruiting

Registration date
01/05/2019

Overall study status
Completed

Last Edited
03/03/2022

Condition category
Musculoskeletal Diseases

[X] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

Plain English summary of protocol
Background and study aims
Rotator cuff (RC) disease is among the most common musculoskeletal disorders. Patients with RC pathology may complain of symptoms ranging from minimal discomfort without functional deficits to severe pain, weakness, and marked disability. The aim of this study is to compare surgical and conservative treatment of RCT, in term of functional outcomes, rotator cuff (RC) integrity, and muscle atrophy or fatty degeneration, to evaluate treatment effectiveness and obtain high-quality evidence for the management of those patients.

Who can participate?
Patients of aged 18 or over with atraumatic, symptomatic, isolated full-thickness supraspinatus tendon tear documented with MRI; full range of motion of the shoulder.

What does the study involve?
To be randomized to surgical and conservative treatment of degenerative RCT.

What are the possible benefits and risks of participating?
It is hoped that the insight gained will help to inform how best to approach RC disease. The results will be published to inform further research into the effectiveness of rehabilitation versus surgical repair of the RC. No additional risks to participants in either treatment group are anticipated.

Where is the study run from?
University Campus Bio-Medico of Rome- Italy.

When is the study starting and how long is it expected to run for?
May 2019 until April 2022.

Who is funding the study?
University Campus Bio-Medico of Rome and the Italian Ministry of Health ((Ricerca FINALIZZATA 2016 - PE-2016-02364894).

Who is the main contact?
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Contact information

Type(s)
Public

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Additional identifiers

Protocol serial number
19/18 PAR ComEt CBM

Study information

Scientific Title
Surgical versus conservative management for patients with rotator cuff tears: a randomized controlled trial

Acronym
SUN

Study objectives
There will be no differences between surgical and conservative treatment of rotator cuff tears, in term of functional outcomes, rotator cuff integrity, and muscle atrophy or fatty degeneration.

Ethics approval required
Old ethics approval format

Ethics approval(s)
University Campus Bio-Medico of Rome Ethic Committee, 29/03/2018, ref. 19/18 PAR ComEt CBM.

Primary study design
Interventional

Study design
Randomised Controlled Trial

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Rotator Cuff tears

Interventions
Surgical treatment:
Patients in group 1 will undergo an arthroscopic rotator cuff repair

Conservative treatment:
Conservative treatment will consist of a validated protocol for conservative RC rehabilitation (http://www.moonshoulder.com/booklets/060109PatientRehabBooklet.pdf) under the supervision of an experienced shoulder physiotherapist.

Total duration of treatment:
3 months

Follow-up for all study arms
Follow up at 6, 12, and 24 months

Details of the randomisation process:
Patients will be randomly assigned to surgical repair (Group 1) or conservative treatment (Group 2) using a computer-generated allocation, stratified for age, gender, and affected shoulder (right or left).

Intervention Type
Procedure/Surgery

Primary outcome(s)
Pain and ability to carry out normal daily activities will be measured using the constant score at 6, 12, and 24 months.

Key secondary outcome(s)
1. Shoulder function will be measured using the ASES Shoulder Score at 6, 12, and 24 months
2. Pain will be measured using the VAS at 6, 12, and 24 months.
3. Patient-reported outcomes will be measured using the Oxford Shoulder Score at 6, 12, and 24 months.
4. Rotator cuff integrity, the extent of fatty degeneration and the amount of muscle atrophy will be measured using an MRI at 6, 12 and 24 months post-operatively.
5. Shoulder pain and disability will be measured using the Shoulder Pain And Disability Index at 6, 12, and 24 months.
6. Pain-related disability will be measured using the Shoulder Disability Questionnaire at 6, 12, and 24 months.
7. Shoulder symptoms and function will be measured using the Shoulder Rating Questionnaire at

6, 12, and 24 months.
8. General health will be measured using the Short-Form 36 at 6, 12, and 24 months.

Completion date
31/12/2024

Eligibility

Key inclusion criteria
1. Atraumatic, symptomatic, isolated full-thickness supraspinatus tendon tear documented with MRI
2. Full passive range of motion of the shoulder.

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
All

Key exclusion criteria
1. Previous surgical treatment of the shoulder
2. Frozen shoulder
3. Radiological osteoarthritis of the glenohumeral joint
4. Cognitive disorders
5. Neurological disease or language barriers
6. Tear involving the whole supraspinatus tendon combined with tear of two to three tendons
7. Muscle fatty degeneration > of stage 2 according to Goutallier classification
8. Muscle atrophy evaluated with Tangent sign, exceeding stage 2
9. Acute-on-chronic tears (after a traumatic event in a shoulder with preceding episodes of symptoms)

Date of first enrolment
07/01/2021

Date of final enrolment
31/12/2024

Locations

Countries of recruitment
Italy

Study participating centre
University Campus Bio-Medico of Rome
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Sponsor information

Organisation
Campus Bio-Medico University of Rome

ROR
https://ror.org/04gqx4x78

Funder(s)

Funder type
University/education

Funder Name
Università Campus Bio-Medico di Roma

Alternative Name(s)
Campus Bio-Medico University

Funding Body Type
Private sector organisation

Funding Body Subtype
Universities (academic only)

Location
Italy

Funder Name
Italian Ministry of Health (Ricerca Finalizzata)

Results and Publications

Individual participant data (IPD) sharing plan

The data sharing plans for the current study are unknown and will be made available at a later date.

IPD sharing plan summary

Data sharing statement to be made available at a later date