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Tailored postoperative care for rotator cuff pathologies

Submission date
09/08/2023

Recruitment status
Recruiting

Registration date
03/10/2023

Overall study status
Ongoing

Last Edited
23/01/2026

Condition category
Musculoskeletal Diseases

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

Plain English summary of protocol

Background and study aims
It's hard to make sure patients follow and stick to their post-surgery recovery program, and this can affect the final results. In a past research study, we used a wearable system with special sensors to keep track of how patients were doing their recovery exercises after shoulder surgery (rotator cuff repair). Even though doctors told them how to do their exercises, people did them in a lot of different ways. The results of this study helped us find a new plan for physical therapy that gave better results for patients' health and recovery. But we haven't yet tested how well this new plan works in a big study. So, in this new study, we want to compare the new recovery plan to the usual care that patients get after shoulder surgery, and see which one works better.

Who can participate?
Patients aged 45 - 70 years undergoing surgical rotator cuff repair

What does the study involve?
Once we have all the patients who meet the criteria and they agree to be in the study, we will do some tests like MRI scans, movement analysis, and clinical evaluations using scores before their surgery. A skilled orthopedic surgeon will perform the needed surgery on all patients, fixing their shoulder using arthroscopic methods.

After the surgery, a certified researcher will tell the patients which group they are in: Group 1 gets the usual care, while Group 2 tries the new approach. The patients will come back for check-ups at 6 weeks and 3 months after surgery. We will use scores to evaluate their progress (CMS, ASES, SF-36, VAS).

Later, at 6 months and 12 months after the surgery, we will do more check-ups using scores (CMS, ASES, SF-36, VAS), do more tests like MRI scans and movement analysis, to see how well they are recovering.

What are the possible benefits and risks of participating?
The expected results of this study could offer the prospect of providing high value care and reducing costs to the National Health System associated with ineffective aftercare, with immediate benefits for patients. There are no direct risks for the patients recruited in the study.

Where is the study run from?
Fondazione Policlinico Universitario Campus Bio-Medico (Italy)

When is the study starting and how long is it expected to run for?
January 2023 to December 2030

Who is funding the study?
Fondazione Policlinico Universitario Campus Bio-Medico (Italy)
Ministero della Salute (Italy)

Who is the main contact?
Prof. Umile Giuseppe Longo, g.longo@policlinicocampus.it

Contact information

Type(s)
Principal investigator

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

Protocol serial number
0035/23 PAR ComEt CBM, Ricerca Finalizzata RF-2021-12372810

Study information

Scientific Title
Tailored postoperative care for rotator cuff pathologies: a randomized controlled trial

Acronym
CARE-RC

Study objectives

Adherence to an optimized rehabilitation protocol will reduce the number of rotator cuff re-tears and will improve clinical outcomes.

Ethics approval required
Ethics approval required

Ethics approval(s)
approved 30/01/2023, Università Campus Bio-Medico di Roma (Via alvaro del portillo, 200, Roma, 00128, Italy; +39 6225418718; comitato.etico@policlinicocampus.it), ref: 0035/23 PAR ComEt CBM

Study design
Two-arm monocentric randomized controlled trial

Primary study design
Interventional

Study type(s)
Efficacy, Quality of life

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

Interventions
After the enrollment of all the patients satisfying the inclusion criteria and after obtaining consent for the study participation, patients will undergo structural evaluation (MRI), kinematic analysis, and clinical assessment (clinical scores) before surgery. An experienced orthopedic surgeon will perform surgical procedures in all the patients. The arthroscopic RC repair will be performed.

After surgery, an authorized researcher will inform the enrolled patients of the treatment allocation (Group 1 - standard of care, Group 2 - experimental group). Patients will undergo clinical and functional assessments during follow-up visits at 6-weeks and 3-months after surgery using clinical scores (CMS, ASES, SF-36, VAS). At 6-months and 12-months after surgery, patients will undergo clinical and functional assessments using clinical scores (CMS, ASES, SF-36, VAS), structural evaluation (MRI), and kinematic analysis.

Patients will be assigned to each group using a computer-generated list of random numbers. An independent researcher responsible for data management will organize the treatment allocation and will provide sealed and numbered envelopes to the head nurse before surgery. The envelope will be opened only at the end of the surgical procedure. Therefore, the orthopedic surgeon will be blinded to the randomization assignment. The same independent researcher will inform the enrolled patients of the treatment allocation.

Intervention Type
Procedure/Surgery

Primary outcome(s)

Before surgery and at 6-months and 12-months after surgery:
1. Structural data are measured by structural evaluation (MRI)
2. Kinematic variables (such as range of motion, angular velocity) are measured by kinematic analysis

Key secondary outcome(s))
Clinical data evaluated before surgery and at 6-weeks, 3-months, 6- months, and 12-months after surgery:
1. Physical and subjective measures of the affected shoulder in terms of pain, activities of daily living (ADL), range of motion (ROM), and strength are measured by CMS.
2. Patient self-reported and clinician scores about pain, ADL, ROM, signs, strength, and instability are measured by ASES.
3. The quality of life and mental health (such as physical and social functioning, general health perception limitations due to emotional aspects, vitality) are measured by SF-36.
4. The level of pain perceived by patients are measured by VAS.

Completion date
31/12/2030

Eligibility

Key inclusion criteria
1. Age 45-70 years.
2. Atraumatic, symptomatic, isolated full-thickness supraspinatus tendon tear documented with MRI.
3. No surgical treatment to the affected shoulder before.
4. No episodes of shoulder instability.
5. No radiographic signs of fracture of the glenoid fossa or the greater or lesser tuberosity.

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Mixed

Lower age limit
45 years

Upper age limit
70 years

Sex
All

Total final enrolment
0

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

Date of first enrolment
21/12/2023

Date of final enrolment
31/12/2029

Locations

Countries of recruitment
Italy

Study participating centre
Fondazione Policlinico Universitario Campus Bio-Medico
Via Alvaro del Portillo, 200
Roma
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Sponsor information

Organisation
Fondazione Policlinico Universitario Campus Bio-Medico

Funder(s)

Funder type
Government

Funder Name
Ministero della Salute

Alternative Name(s)
Italian Ministry of Health, Italy Ministry of Health, Ministry of Health of Italy, Ministry of Health - Italy, Ministry of Health, Italy

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
Italy

Funder Name
Fondazione Policlinico Universitario Campus Bio-Medico

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Data sharing statement to be made available at a later date