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# Growth factors augmentation for arthroscopic rotator cuff repair

| Submission date | Recruitment status | [ ] Prospectively registered |
|---|---|---|
| 06/01/2010 | No longer recruiting | [ ] Protocol |
| **Registration date** | **Overall study status** | [ ] Statistical analysis plan |
| 02/02/2010 | Completed | [ ] Results |
| **Last Edited** | **Condition category** | [ ] Individual participant data |
| 02/02/2010 | Injury, Occupational Diseases, Poisoning | [ ] Record updated in last year |

**Plain English summary of protocol**
Not provided at time of registration

## Contact information

**Type(s)**
Scientific

**Contact name**
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## Additional identifiers

**Protocol serial number**
N/A

## Study information

**Scientific Title**
Efficacy and safety of growth factors augmentation for arthroscopic rotator cuff repair compared with non-augmented repair: a randomised controlled trial

**Study objectives**

To test the hypothesis that growth factors augmentation results in increased improvement in shoulder function and better magnetic resonance imaging (MRI) appearance in patients undergoing arthroscopic repair of small or moderate rotator cuff tears.

## Ethics approval required
Old ethics approval format

## Ethics approval(s)
Local ethics committee (Comitato etico dellOspedale di Iesi, ASUR MARCHE) approved on the 2nd January 2007

## Study design
Interventional randomised single centre single-blind placebo-controlled cross-over study

## Primary study design
Interventional

## Study type(s)
Treatment

## Health condition(s) or problem(s) studied
Rotator-cuff tendon tear

## Interventions
Study group:
Arthroscopic rotator cuff repair and augmentation with platelet-rich fibrin matrix (Cascade® Autologous Platelet System, Musculoskeletal Transplant Foundation [MTF]).

Control group:
Arthroscopic rotator cuff repair without augmentation with platelet-rich fibrin matrix (Cascade® Autologous Platelet System, MTF).

## Intervention Type
Other

## Phase
Not Applicable

## Primary outcome(s)
Difference in change from baseline to 16 months in the Constant Score between the two groups. The Constant Score is a scoring system shoulder rating scale evaluating shoulder pain (15 points), activities of daily living (20 points), range of movement (40 points), and power (25 points). Total possible score is 100 points, indicating an asymptomatic and healthy person, while the worst score is 0 points.

## Key secondary outcome(s))
Integrity of the repaired rotator cuff, as evaluated by MRI.

## Completion date
28/04/2008

# Eligibility

### Key inclusion criteria
1. Aged over 30 years, either sex
2. Rotator cuff tear diagnosed on clinical grounds
3. No episodes of shoulder instability
4. No radiographic signs of fracture of the glenoid or the greater or lesser tuberosity
5. Magnetic resonance imaging evidence of cuff tear
6. A repairable full-thickness tear of the rotator cuff found at the time of surgery
7. Patients with associated biceps pathology are also included

### Participant type(s)
Patient

### Healthy volunteers allowed
No

### Age group
Adult

### Sex
All

### Key exclusion criteria
1. Inflammatory joint disease
2. Irreparable full-thickness tear or partial thickness tear of the rotator cuff found at the time of surgery
3. Symptomatic arthritis of the acromioclavicular joint
4. Rotator cuff arthropathy
5. Pathologies of the subscapularis tendon
6. Workers' Compensation claims
7. Prior surgery on the affected shoulder
8. Inability to complete questionnaires because of language problem

### Date of first enrolment
03/01/2007

### Date of final enrolment
28/04/2008

# Locations

### Countries of recruitment
Italy

### Study participating centre
**Asur marche**
Jesi

Italy
60010

# Sponsor information

**Organisation**
Ospedale Civile (Italy)

**ROR**
https://ror.org/01nsxt963

# Funder(s)

**Funder type**
Hospital/treatment centre

**Funder Name**
Ospedale di Jesi (Italy)

# Results and Publications

**Individual participant data (IPD) sharing plan**

**IPD sharing plan summary**
Not provided at time of registration

**Study outputs**

| Output type | Details | Date created | Date added | Peer reviewed? | Patient-facing? |
|---|---|---|---|---|---|
| Participant information sheet | Participant information sheet | 11/11/2025 | 11/11/2025 | No | Yes |