

Growth factors augmentation for arthroscopic rotator cuff repair

Submission date

06/01/2010

Recruitment status

No longer recruiting

☐ Prospectively registered

☐ Protocol

Registration date

02/02/2010

Overall study status

Completed

☐ Statistical analysis plan

☐ Results

Last Edited

02/02/2010

Condition category

Injury, Occupational Diseases, Poisoning

☐ Individual participant data

☐ Record updated in last year

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

Dr Roberto Castricini

Contact details

Asur marche

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Jesi

Italy

60010

Additional identifiers

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 dell'Ospedale di Jesi, ASUR MARCHE) approved on the 2nd January 2007

Primary study design

Interventional

Study design

Interventional randomised single centre single-blind placebo-controlled cross-over study

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