

Growth factors augmentation for arthroscopic rotator cuff repair

Submission date 06/01/2010	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
Registration date 02/02/2010	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 02/02/2010	Condition category Injury, Occupational Diseases, Poisoning	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> Record updated in last year

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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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 dell'Ospedale di lesi, 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