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Growth factors augmentation for arthroscopic rotator cuff repair

Submission date	Recruitment status
06/01/2010	No longer recruiting
Registration date	**Overall study status**
02/02/2010	Completed
Last Edited	**Condition category**
02/02/2010	Injury, Occupational Diseases, Poisoning

- [ ] Prospectively registered
- [ ] Protocol
- [ ] Statistical analysis plan
- [ ] Results
- [ ] Individual participant data
- [ ] 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

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

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 measure
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.

Secondary outcome measures
Integrity of the repaired rotator cuff, as evaluated by MRI.

Overall study start date
03/01/2007

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

Age group
Adult

Sex
Both

Target number of participants
82 participants (41 participants per group)

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)

Sponsor details
Viale della Vittoria n.76
Jesi
Italy
60035

Sponsor type
Hospital/treatment centre

Website
http://www.asurzona5.marche.it

ROR
https://ror.org/01nsxt963

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Ospedale di Jesi (Italy)

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration