ISRCTN93082180 https://doi.org/10.1186/ISRCTN93082180

The use of platelet-leukocyte membrane in arthroscopic repair of large rotator cuff tear

Submission date
16/12/2010

Recruitment status
No longer recruiting

Registration date
28/02/2011

Overall study status
Completed

Last Edited
28/02/2011

Condition category
Musculoskeletal Diseases

[ ] 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

Study information

Scientific Title
The use of platelet-leukocyte membrane in arthroscopic repair of large rotator cuff tear: a prospective randomised controlled study

Study objectives
The purpose of this study was to evaluate the clinical and magnetic resonance imaging (MRI) results of single-row arthroscopic rotator cuff repair with and without the employment of platelet-leukocyte membrane in patients with large postero-superior cuff tear.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics Board of the University of Rome "Sapienza" and Policlinico Umberto I approved in 2008 (ref: 2/08)

Primary study design
Interventional

Study design
Prospective randomised controlled study

Study type(s)
Treatment

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

Interventions
Group I: arthroscopic rotator cuff repair using platelet-leukocyte membrane
Group II (control): arthroscopic rotator cuff repair without platelet-leukocyte membrane

The total approximate duration of treatment was 18 months, considering first clinical exam /diagnosis, operation, follow up at 3 and 6 months and final follow-up with clinical exam and MRI of the involved shoulder.

Intervention Type
Other

Phase
Not Applicable

Primary outcome(s)
To evaluate the clinical (Constant score and SST) and MRI results (Sugaya's scale) of single-row arthroscopic rotator cuff repair with and without the employment of platelet-leukocyte membrane in patients with large postero-superior cuff tear. To test the hypothesis that the use of platelet-leukocyte membrane provided superior clinical results in terms of repair integrity, a chi square test was used. Significance level p was set at 0.05

Key secondary outcome(s)
Comparison between the two groups. Group I: arthroscopic rotator cuff repair using platelet-leukocyte membrane. Group II (control) arthroscopic rotator cuff repair without platelet-leukocyte membrane

Completion date
11/10/2010

Eligibility

Key inclusion criteria
1. Large repairable full-thickness rotator cuff tear
2. Ability of the patient to complete serial MRI examination
3. Aged over 18 years, either sex

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 Years

Sex
All

Key exclusion criteria
1. A partial thickness
2. Small or massive full-thickness tear
3. Subscapularis tear
4. Severe biceps lesions or biceps instability
5. Labral pathology ameable for surgical repair
6. Os acromiale
7. Degenerative arthritis of the gleno-humeral joint
8. Autoimmune or rheumatological diseases
9. Previous surgery in the same shoulder
10. Worker's compensation claims

Date of first enrolment
19/05/2008

Date of final enrolment
11/10/2010

Locations

Countries of recruitment
Italy

Study participating centre
Via Tacito, 74
Rome
Italy
00193

Sponsor information

Organisation
Orthopaedic Clinic University of Rome "Sapienza" (Italy)

ROR
https://ror.org/02be6w209

Funder(s)

Funder type
University/education

Funder Name
Sapienza University of Rome (Italy)

Alternative Name(s)
Sapienza University of Rome, Università degli Studi di Roma "La Sapienza”, Sapienza-Università di Roma, Sapienza, Uniroma1

Funding Body Type
Government organisation

Funding Body Subtype
Universities (academic only)

Location
Italy

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration