

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

Submission date 16/12/2010	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
Registration date 28/02/2011	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
Last Edited 28/02/2011	Condition category Musculoskeletal Diseases	<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

Contact name
Prof Stefano Gumina

Contact details
Via Tacito, 74
Rome
Italy
00193
s.gumina@tiscali.it

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

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)

Study design

Prospective randomised controlled study

Primary study design

Interventional

Secondary study design

Non 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 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 measure

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

Secondary outcome measures

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

Overall study start date

19/05/2008

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

Age group

Adult

Lower age limit

18 Years

Sex

Both

Target number of participants

80 consecutive patients

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 amenable 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)

Sponsor details

c/o Prof Franco Postacchini

Piazzale Aldo Moro, 5

Rome

Italy

00185

Sponsor type

University/education

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

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