

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

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		<input type="checkbox"/> Protocol
<b>Registration date</b> 28/02/2011	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
<b>Last Edited</b> 28/02/2011	<b>Condition category</b> 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

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## 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