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Efficacy of a target platelet concentration in platelet-rich plasma for arthroscopic rotator cuff repair

Submission date
24/09/2026

Recruitment status
No longer recruiting

Registration date
25/09/2026

Overall study status
Completed

Last Edited
25/09/2026

Condition category
Surgery

[_] Prospectively registered
[X] Protocol
[X] Statistical analysis plan
[_] Results
[_] Individual participant data
[X] Record updated in last year

Plain English summary of protocol

Background and study aims
The rotator cuff is a group of muscles and tendons that help to move and support the shoulder. A tear in one of these tendons, called the supraspinatus tendon, can cause pain and problems with shoulder function. If other treatments do not help, the tendon may be repaired using keyhole surgery.
Platelet-rich plasma (PRP) is made from a person's own blood and contains a high concentration of platelets. It is sometimes used to support healing after surgery. This study looked at whether using PRP with a specific concentration of platelets during rotator cuff surgery could help the repaired tendon to heal. It also looked at shoulder function, pain and complications after surgery.

Who can participate?
Patients aged over 18 years who needed keyhole surgery to repair a supraspinatus tendon tear that had not improved with non-surgical treatment could take part. Participants needed to be able to follow a standard rehabilitation programme after surgery and provide written consent to take part and receive PRP.
People could not take part if they had previously had surgery on the same shoulder or had certain other conditions affecting the shoulder or arm, such as a previous fracture, tumour, infection or arthritis. People with traumatic rotator cuff tears and some other types or severities of shoulder damage could also not take part.

What does the study involve?
All participants had keyhole surgery to repair the torn supraspinatus tendon. During the procedure, they also received an injection of PRP prepared from their own blood.
A small amount of blood was taken, similar to a routine blood test. The blood was then processed in a machine to separate the part containing a high concentration of platelets. The PRP was prepared to achieve a target concentration before being used during the operation. A small sample was kept to measure the concentrations of different blood cells and was then disposed of according to standard procedures.
Participants were followed for 6 months. The researchers assessed whether the repaired tendon had healed at 6 months. They also measured shoulder function and pain. Pain was assessed at 1

month and 6 months after surgery, and shoulder function was assessed at 6 months. Taking part did not require any extra hospital visits or tests beyond those normally carried out for this type of surgery.

What are the possible benefits and risks of participating?
The PRP treatment may help the repaired tendon to heal, although this cannot be guaranteed. The information collected may also help researchers understand whether PRP prepared to a specific platelet concentration is useful in rotator cuff repair.
PRP was made from each participant's own blood. The main additional discomfort expected from taking part was having blood taken once to prepare the PRP. This was usually done shortly before anaesthesia. The study did not require additional visits or tests beyond usual care.

Where is the study run from?
The study was run at Centro Hospitalar Universitário S. João in Porto, Portugal.

When is the study starting and how long is it expected to run for?
May 2024 to 20 February 2026.

Who is funding the study?
The study was initiated and funded by the investigators.

Who is the main contact?
Dr Bernardo Nunes at Hospital de São João in Porto, Portugal.
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Contact information

Type(s)
Principal investigator, Scientific, Public

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Additional identifiers

Study information

Scientific Title

Efficacy of a target platelet concentration in platelet-rich plasma for arthroscopic rotator cuff repair: a single-arm phase II clinical trial

Study objectives
The aim of this study was to evaluate the efficacy of a target platelet concentration for PRP in aRCR, with tendon healing as the primary outcome. Secondary outcomes were also considered, including overall function—assessed via the Subjective Shoulder Value (SSV) and the Constant-Murley Score (CMS)—pain (Visual Analogue Scale (VAS)), and post-operative complications.

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 09/11/2023, S. João University Hospital Ethics Committee (Alameda Prof. Hernani Monteiro, Porto, 4200, Portugal; +351 225512100; comissao.etica@ulssjoao.min-saude.pt), ref: Ref 279/2023

Primary study design
Interventional

Allocation
N/A: single arm study

Masking
Blinded (masking used)

Control
Uncontrolled

Assignment
Sequential

Purpose
Treatment

Study type(s)

Health condition(s) or problem(s) studied
Arthroscopic repair of supraspinatus tears

Interventions
Arthroscopic repair of the supraspinatus using a double-row technique and injection of a commercial preparation of PRP (Angel System, Arthrex, Naples, FL, USA), using a standardized protocol to reach a target dose of approximately 1160.27 × 10^3/μL and a white blood cell (WBC) macrophage-depleted concentration of 11.69 × 10^3/μL, including a neutrophil (NE) concentration of 2.84 × 10^3/μL. Patients were followed up for 6 months.

Intervention Type
Biological/Vaccine

Phase
Phase II

Drug/device/biological/vaccine name(s)
Platelet Rich Plasma - Angel System Arthrex

Primary outcome(s)
1. Healing status measured using Sugaya classification at 6 months follow-up

Key secondary outcome(s)
1. Subjective shoulder function measured using subjective shoulder value at 6 months post-operatively

2. Pain measured using VAS at 1 month and 6 months post-operatively

3. Shoulder function (subjective + objective) measured using Constant-Murley Score at 6 months post-operatively

Completion date
20/02/2026

Eligibility

Key inclusion criteria
1. Aged over 18 years
2. An indication for supraspinatus arthroscopic rotator cuff repair (aRCR) due to tears refractory to conservative management
3. Able to comply with a standardised postoperative rehabilitation protocol
4. Provided written informed consent for study participation and platelet-rich plasma (PRP) administration

Healthy volunteers allowed
No

Age group
Mixed

Lower age limit
18 Years

Upper age limit
99 Years

Sex
All

Total final enrolment
37

Key exclusion criteria

1. Prior surgery on the ipsilateral shoulder
2. A history of fracture, tumour, or infection in the ipsilateral upper limb
3. Fatty infiltration of Goutallier grade IV of the supraspinatus or infraspinatus
4. Glenohumeral arthritis
5. Rotator cuff arthropathy greater than Hamada grade II
6. Concomitant subscapularis tears ≥ Lafosse grade III
7. Traumatic rotator cuff tears (RCTs)

Date of first enrolment
13/05/2024

Date of final enrolment
19/08/2025

Locations

Countries of recruitment
Portugal

Study participating centre
Centro Hospitalar Universitário S. João
Alameda Prof Hernani Monteiro
Porto
Portugal
4200

Sponsor information

Organisation
Hospital de São João

ROR
https://ror.org/04qsnc772

Funder(s)

Funder type

Funder Name
Investigator initiated and funded

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	in Portuguese		25/09/2026	No	Yes
Protocol file			25/09/2026	No	No
Statistical Analysis Plan			25/09/2026	No	No