

# Platelet rich plasma and rotator cuff tendons

<b>Submission date</b> 11/01/2011	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
<b>Registration date</b> 29/03/2011	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 27/10/2015	<b>Condition category</b> Injury, Occupational Diseases, Poisoning	<input type="checkbox"/> Individual participant data

## Plain English summary of protocol

Not provided at time of registration

## Contact information

### Type(s)

Scientific

### Contact name

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## Additional identifiers

### Protocol serial number

Version 1

## Study information

### Scientific Title

A randomised controlled trial to assess the effectiveness of treating subacromial impingement and partial thickness rotator cuff tears with the administration of Platelet Rich Plasma during arthroscopic decompression surgery

## **Acronym**

PaROT

## **Study objectives**

The study objective is to assess the effectiveness of treating subacromial impingement and partial thickness rotator cuff tears with the administration of Platelet Rich Plasma during arthroscopic decompression surgery by comparing the outcomes with standard arthroscopic subacromial decompression surgery.

## **Ethics approval required**

Old ethics approval format

## **Ethics approval(s)**

Oxfordshire Research Ethics Committee (REC) C, 11/10/2010, ref: 10/H0606/60

## **Study design**

Randomised controlled trial

## **Primary study design**

Interventional

## **Study type(s)**

Treatment

## **Health condition(s) or problem(s) studied**

Rotator cuff impingement and tears

## **Interventions**

Subacromial decompression:

Subacromial decompression surgery is performed under general anaesthetic. The procedure involves insertion of the arthroscope into the glenohumeral joint where the joint surface is inspected along with the intra-articular portion of the long head of biceps and the joint surface of the rotator cuff tendons. Once this has been performed the arthroscope is removed and inserted into the sub-acromial bursa which lies outside the rotator cuff tendons and beneath the acromion process of the scapula. In the bursa the acromion and superior surface of the rotator cuff are assessed to ensure the coracoacromial ligament and the acromioclavicular (AC) joint remains intact. The projecting under surface of the distal part of the acromion is resected. The intervention is considered a well established and well documented procedure. Patients with full cuff tears noted at the time of surgery will not be eligible and will be excluded at operation.

Subacromial decompression and platelet-rich plasma (PRP):

This group will receive the same operation as described above plus an autologous PRP concentrate injection into the rotator cuff tendon during surgery. PRP can be applied in a variety of methods: as a gel, as an injection, as a sutured film during surgery, sprayed directly onto repaired tissue, or injected subcutaneously. This study proposes the use of a gel sprayed directly to the decompression area.

Specific preparation techniques will be stipulated by the company providing the PRP device.

Methodology:

Patients will be identified in, and recruited from, the shoulder outpatient clinics at the Nuffield

Orthopaedic Centre NHS Trust, Oxford. Diagnosis of shoulder impingement or partial thickness tear will be confirmed with ultrasound in the clinic and the patient will be put on the waiting list for surgery. A surgical member of the research team will introduce the trial to the patient and refer them to a research nurse for recruitment.

The research nurse will explain the study to the patient and provide them with written information about their involvement in the study. If the patient is willing they will be asked to 'opt-in' to the study by signing a 'preliminary' consent form. The patient will not formally have been recruited to the study at this point but in order to establish their eligibility to enter the study their routine pre-operative blood test results will need to be reviewed and permission to do so obtained.

They will be contacted by telephone a few days later to discuss the study further. If the patient is happy to participate at the time of the telephone call, they will be asked to review the study information pack provided at their clinic visit and bring this with them on their day of surgery; should they be ineligible for the study this information can be simply discarded. On their day of surgery they will sign a full consent form, complete a baseline questionnaire and undergo a baseline clinical assessment (including Oxford Shoulder Score) before surgery.

The patient will then be randomised using a computer generated randomisation system. Patients will be stratified by tear status. Routine peri-operative care will proceed and the patient will have their operation as planned. Patients will be followed up in clinic at six weeks and at three and six months post treatment.

### **Intervention Type**

Procedure/Surgery

### **Primary outcome(s)**

Oxford Shoulder Score at 6 months post-treatment

### **Key secondary outcome(s)**

1. Functional shoulder assessments
2. EQ5D
3. Oxford Satisfaction Index

Measured at baseline and 3 weeks, 3 months, 6 months and 12 months post-treatment.

### **Completion date**

30/09/2012

## **Eligibility**

### **Key inclusion criteria**

1. Patients with shoulder impingement syndrome or a partial thickness rotator cuff tear
2. Diagnosis confirmed using ultrasound scan by a trained member of the research team
3. Failed conservative treatment
4. Listed for arthroscopic subacromial decompression
5. Male or female, aged 35 - 75 years old

### **Participant type(s)**

Patient

**Healthy volunteers allowed**

No

**Age group**

Adult

**Sex**

All

**Key exclusion criteria**

1. Full thickness rotator cuff tears
2. Participants with a history of significant trauma (fracture, dislocation/instability, etc.), surgery, osteoarthritis or other significant pathology of the affected shoulder not related to the rotator cuff
3. Patient is unable to consent for themselves
4. No conservative treatment
5. Previous surgery on affected surgery
6. Contraindications to PRP (listed below):
  - 6.1. History of diabetes mellitus
  - 6.2. Platelet abnormality or platelets count less than  $100 \times 10^9/l$
  - 6.3. Haematological disorder
  - 6.4. Serum haemoglobin less than 11 g/dl
  - 6.5. Use of systemic cortisone
  - 6.6. Use of any anticoagulant
  - 6.7. Evidence of gangrene/ulcers or peripheral vascular disease
  - 6.8. History of hepatic or renal impairment or dialysis
  - 6.9. Patient is known to have a psychological, developmental, physical, emotional or social disorder that may interfere with compliance with study requirements
  - 6.10. History of alcohol or drug abuse
  - 6.11. Patient has a religious or cultural conflict with the use of platelet gel treatment or blood products
  - 6.12. Patient has inadequate venous access for blood draw
  - 6.13. Patient is currently receiving or has received radiation or chemotherapy within the last 3 months prior to the study
  - 6.14. Female participants who are pregnant, lactating or planning pregnancy during the course of the study
  - 6.15. Any other significant disease or disorder which, in the opinion of the Investigator, may either put the participants at risk because of participation in the study, or may influence the result of the study, or the participant's ability to participate in the study

**Date of first enrolment**

01/10/2010

**Date of final enrolment**

30/09/2012

**Locations****Countries of recruitment**

United Kingdom

England

### Study participating centre

NDORMS

Oxford

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## Sponsor information

### Organisation

University of Oxford (UK)

### ROR

<https://ror.org/052gg0110>

## Funder(s)

### Funder type

University/education

### Funder Name

University of Oxford (UK) - Nuffield Department of Orthopaedic, Rheumatology and Musculoskeletal Sciences

## Results and Publications

### Individual participant data (IPD) sharing plan

### IPD sharing plan summary

Not provided at time of registration

### Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Results article</a>	results	01/12/2015		Yes	No
<a href="#">Protocol article</a>	protocol	11/06/2013		Yes	No
<a href="#">Participant information sheet</a>	Participant information sheet	11/11/2025	11/11/2025	No	Yes

