

Platelet rich plasma and rotator cuff tendons

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

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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

Secondary study design

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 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 measure

Oxford Shoulder Score at 6 months post-treatment

Secondary outcome measures

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.

Overall study start date

01/10/2010

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

Age group

Adult

Sex

Both

Target number of participants

34

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

England

United Kingdom

Study participating centre

NDORMS

Oxford

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Sponsor information

Organisation

University of Oxford (UK)

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Sponsor type

University/education

Website

<http://www.ox.ac.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

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

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	protocol	11/06/2013		Yes	No
Results article	results	01/12/2015		Yes	No