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Platelet rich plasma and rotator cuff tendons

Submission date	Recruitment status	[_] Prospectively registered
11/01/2011	No longer recruiting	[X] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
29/03/2011	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
27/10/2015	Injury, Occupational Diseases, Poisoning	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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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 wtih 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 wtih 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

Primary study design
Interventional

Study design
Randomised controlled trial

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 x 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
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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?
Results article	results	01/12/2015		Yes	No
Protocol article	protocol	11/06/2013		Yes	No