

# Platelet rich plasma in Accelerated Tendo-achilles Healing

<b>Submission date</b> 10/11/2009	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered
<b>Registration date</b> 18/01/2010	<b>Overall study status</b> Completed	<input type="checkbox"/> Protocol
<b>Last Edited</b> 18/01/2010	<b>Condition category</b> Injury, Occupational Diseases, Poisoning	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
		<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

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## Additional identifiers

**Protocol serial number**  
PATH v2.0

## Study information

## **Scientific Title**

PATH: a prospective, randomised, controlled trial to investigate the clinical efficacy of platelet rich plasma in accelerating acute achilles tendon rupture healing and comparing it to traditional cast immobilisation treatment or operative treatment

## **Acronym**

PATH

## **Study objectives**

Null hypothesis: Platelet rich plasma or concentrates do not accelerate the rate of acute achilles tendon rupture healing and do not reduce the risk of re-rupture following non-operative or operative treatment.

## **Ethics approval required**

Old ethics approval format

## **Ethics approval(s)**

Oxfordshire Ethics Committee B approved on the 21st July 2009 (ref: 09/H0605/78)

## **Study design**

Parallel double arm double blinded individually randomised controlled efficacy trial

## **Primary study design**

Interventional

## **Study type(s)**

Treatment

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

Acute achilles tendon rupture

## **Interventions**

Patients will follow a conservative or operative pathway according to the established protocol, which is determined depending on the tendo-achilles (TA) rupture gap size measured by ultrasound scan (USS). Patients in each arm of the trial will be randomised into one of two groups using sequentially numbered opaque envelopes or computer generated randomisation:

Conservative treatment arm (rupture gap less than 5 mm):

1. Standard cast immobilisation group
2. Platelet rich plasma (PRP) and standard cast immobilisation group

Operative treatment arm (rupture gap greater than 5 mm):

3. Standard surgical repair group
4. Platelet rich plasma (PRP) and standard surgical repair group

PRP is applied once only and total follow-up time is 1 year. Patients in all groups will be asked to complete Achilles Tendon Rupture Score (ATRS) questionnaire and other outcome measures questionnaire in the follow up outpatient clinic. The change in the ATRS is the clinical outcome measures. In addition, Functional UltraSound Elastography Scan will be performed to determine the stiffness of the healing tendon in all groups at each visit. Objective assessment of the range of motion (ROM), maximum tip toeing and muscle strength will be measured at 3 and 6 months.

**Intervention Type**

Drug

**Phase**

Not Applicable

**Drug/device/biological/vaccine name(s)**

Platelet rich plasma

**Primary outcome(s)**

Achilles tendon Total Rupture Score (ATRS), measured at 1, 3, 6, 8, 12 weeks

**Key secondary outcome(s)**

1. Functional ultrasound elastography scan, measured at 3 and 6 months
2. Foot and Ankle Outcome Score (FAOS), measured at 1, 3, 6, 8, 12 weeks
3. Victorian Institute of Sport Assessment-Achilles questionnaire (VISA-A), measured at 1, 3, 6, 8, 12 weeks
4. Range of movement, measured at 3 and 6 months
5. Maximum tip-toeing, measured at 3 and 6 months
6. 36-item short form health survey (SF-36), measured at 3 and 6 months
7. Re-rupture rate, measured at 3 and 6 months

**Completion date**

01/11/2012

**Eligibility****Key inclusion criteria**

1. Participant is willing and able to give informed consent for participation in the study
2. Male or female, aged 18 - 55 years
3. Diagnosed with acute achilles tendon rupture
4. Presenting within 72 hours post-injury, due to sport activity or low energy hyper-dorsal flexion of the foot
5. Able (in the Investigators opinion) and willing to comply with all study requirements
6. Willing to allow his or her General Practitioner and consultant, if appropriate, to be notified of participation in the study

**Participant type(s)**

Patient

**Healthy volunteers allowed**

No

**Age group**

Adult

**Lower age limit**

18 years

**Sex**

All

### **Key exclusion criteria**

1. Previous tendon injury
2. History of diabetes mellitus (DM)
3. Platelet abnormality or platelets count less than  $100 \times 10^9 /l$
4. Haematological disorder
5. Serum haemoglobin less than 11 g/dl
6. Use of systemic cortisone
7. Use of any anticoagulant
8. Evidence of gangrene/ulcers or peripheral vascular disease
9. History of hepatic or renal impairment or dialysis
10. Patient is known to have a psychological, developmental, physical, emotional or social disorder that may interfere with compliance with study requirements
11. History of alcohol or drug abuse
12. Patient has a religious or cultural conflict with the use of platelet gel treatment or blood products
13. Patient has inadequate venous access for blood draw
14. Patient is currently receiving or has received radiation or chemotherapy within the last 3 months prior to the study
15. Patient has evidence of Charcot foot/ankle joint
16. Female participants who are pregnant, lactating or planning pregnancy during the course of the study
17. 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**

01/11/2009

### **Date of final enrolment**

01/11/2012

## **Locations**

### **Countries of recruitment**

United Kingdom

England

### **Study participating centre**

**Nuffield Department of Orthopaedic Rheumatology and Musculoskeletal Science**

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## **Sponsor information**

## Organisation

University of Oxford (UK)

## ROR

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

## Funder(s)

### Funder type

Government

### Funder Name

National Institute for Health Research (NIHR) (UK) - Oxford Biomedical Research Centre (OxBRC)

## 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="#">Other publications</a>	literature review performed as part of the study at	01/08/2009		Yes	No