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Platelet rich plasma in Accelerated Tendo-achilles Healing

Submission date	Recruitment status	[ ] Prospectively registered
10/11/2009	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
18/01/2010	Completed	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
18/01/2010	Injury, Occupational Diseases, Poisoning	[ ] 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

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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

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

Secondary outcome measures
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

Overall study start date
01/11/2009

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

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
360

Key exclusion criteria
1. Previous tendon injury
2. History of diabetes mellitus (DM)
3. Platelet abnormality or platelets count less than 100 x 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
England

United Kingdom

Study participating centre
Nuffield Department of Orthopaedic Rheumatology and Musculoskeletal Science
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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

Government

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

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?
Other publications	literature review performed as part of the study at	01/08/2009		Yes	No