# Achilles Tendinopathy Management: plateletrich plasma versus eccentric loading programme

Submission date [ ] Prospectively registered Recruitment status 22/12/2009 No longer recruiting [ ] Protocol [ ] Statistical analysis plan Registration date Overall study status 18/02/2010 Completed [X] Results [ ] Individual participant data Last Edited Condition category 05/08/2014 Musculoskeletal Diseases

### Plain English summary of protocol

Not provided at time of registration

### Contact information

### Type(s)

Scientific

#### Contact name

Mr Matthew Costa

#### Contact details

Warwick Medical School Clinical Sciences Research Institute Clifford Bridge Road Coventry United Kingdom CV2 2DX matthew.costa@warwick.ac.uk

## Additional identifiers

Protocol serial number PRF/09/2

## Study information

#### Scientific Title

Achilles Tendinopathy Management: a randomised controlled trial comparing platelet-rich plasma with an eccentric loading programme

### **Acronym**

**ATM** 

### Study objectives

There is no difference in Victorian Institute of Sports Assessment - Achilles (VISA-A) scores at 6 months between patients initially managed with platelet-rich plasma injections compared to patients managed with an eccentric loading programme.

### Ethics approval required

Old ethics approval format

### Ethics approval(s)

Coventry Research Ethics Committee, 20/03/2009, ref: 09/H1210/18

### Study design

Randomised controlled trial

### Primary study design

Interventional

### Study type(s)

Treatment

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

Achilles tendinopathy

#### **Interventions**

Intervention:

Platelet Rich Plasma Injection. The procedure will involve taking 52 ml of whole blood combined with 8 ml of an anti-coagulant which will be immediately centrifuged at 2400 for 12 minutes. After centrifugation the platelet layer (approximately 3 - 5 ml) will be extracted using a syringe and then injected into the Achilles tendinopathy.

### Comparison:

Eccentric Loading Programme, involving two exercises. The first involves the patient being in a standing position with the heel over the edge of a step with the legs straight. The patient then slowly lowers their heels beyond the level of the step. The second exercise follows the same sequence but with the knee slightly bent, to maximise activation of the soleus muscles. These exercises are performed three times a day, 7 days a week for 12 weeks and are progressed as pain allows by adding weight via a back pack.

### Secondary Sponsor Details:

University Hospitals of Coventry and Warwickshire NHS Trust Research and Development Department Clifford Bridge Road Coventry CV4 8UW United Kingdom

### Intervention Type

Other

### **Phase**

Not Applicable

### Primary outcome(s)

VISA-A at 6, 12, 24, 30, 36 and 52 weeks

### Key secondary outcome(s))

EQ-5D and complications at 6, 12, 24, 30, 36 and 52 weeks

### Completion date

01/02/2012

## **Eligibility**

### Key inclusion criteria

- 1. Midsubstance achilles tendinopathy diagnosed clinically through pain on palpation at a level of 2 6 cm above the tendon insertion and ultrasonography
- 2. The tendinopathy will be causing pain during loading activities and limit those activities
- 3. Duration of at least 3 months
- 4. Aged over 18 years, either sex

### Participant type(s)

Patient

### Healthy volunteers allowed

No

### Age group

Adult

### Lower age limit

18 years

### Sex

All

### Key exclusion criteria

- 1. Tendinopathies secondary to systemic conditions such as rheumatoid arthritis and diabetes
- 2. Insertional Achilles tendinopathies
- 3. Pregnancy
- 4. Previous Achilles rupture or surgery
- 5. Dislocation or fracture of the lower limb within the preceeding 12 months

### Date of first enrolment

01/02/2010

### Date of final enrolment

01/02/2012

### Locations

### Countries of recruitment

United Kingdom

England

Study participating centre Warwick Medical School Coventry United Kingdom CV2 2DX

## Sponsor information

### Organisation

University of Warwick (UK)

### **ROR**

https://ror.org/01a77tt86

## Funder(s)

### Funder type

Research organisation

### **Funder Name**

Physiotherapy Research Foundation (UK) (ref: PRF/09/2)

## **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 17/10/2013 Yes No

Participant information sheet