ISRCTN95369715 https://doi.org/10.1186/ISRCTN95369715

Achilles Tendinopathy Management: platelet-rich plasma versus eccentric loading programme

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

Primary study design
Interventional

Study design
Randomised controlled trial

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