

Ruptured Achilles Tendon Trial: Comparing operative and non-operative management for patients with rupture of the Achilles tendon using immediate weight bearing

Submission date 07/07/2010	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
Registration date 11/08/2010	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 19/09/2013	Condition category Injury, Occupational Diseases, Poisoning	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data

Plain English summary of protocol

Not provided at time of registration

Study website

<http://www2.warwick.ac.uk/fac/med/research/csri/orthopaedics/research/primary/rat/>

Contact information

Type(s)

Scientific

Contact name

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Contact details

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

NIHR CRN Study ID: 7416

Study information

Scientific Title

A randomised pilot trial of operative versus non-operative management using immediate weight bearing rehabilitation

Acronym

RAT

Study objectives

There is no difference in Disability Rating Index (DRI) scores at nine months between patients managed operatively compared to patients managed non-operatively using an immediate weight bearing programme.

Ethics approval required

Old ethics approval format

Ethics approval(s)

The Oxfordshire Research Ethics Committee (REC) A approved on the 27th November 2006 (ref: 06/Q1604/168)

Study design

Pilot randomised controlled 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

Achilles tendon rupture

Interventions

1. Operative Management: Method left to the discretion of the operating surgeon, followed by immediate weight bearing within an orthotic boot for eight weeks
2. Non-operative management: Same rehabilitation as above

Secondary Sponsor:

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 measure

Disability Rating Index (DRI) at 2, 6, 12 weeks and 6 and 9 months

Secondary outcome measures

1. EQ-5D
2. Achilles tendon rupture score (ATRS)
3. Complications

All outcomes measured at 2, 6, 12 weeks and 6 and 9 months.

Overall study start date

01/08/2007

Completion date

01/09/2009

Eligibility

Key inclusion criteria

1. Acute Achilles tendon rupture (presentation within 10 days)
2. Over 18 years

Participant type(s)

Patient

Age group

Adult

Lower age limit

18 Years

Sex

Both

Target number of participants

20

Key exclusion criteria

1. Re-rupture
2. Any other serious injuries to either lower limb that would interfere with rehabilitation
3. Poor circulation in the legs
4. Contraindication to surgery

Date of first enrolment

01/08/2007

Date of final enrolment

01/09/2009

Locations

Countries of recruitment

England

United Kingdom

Study participating centre

Warwick Medical School

Coventry

United Kingdom

CV2 2DX

Sponsor information

Organisation

University of Warwick (UK)

Sponsor details

c/o Grants and Contracts Officer

Research Support Services

University House

Kirby Corner Road

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England

United Kingdom

CV4 8UW

n.k.bains@warwick.ac.uk

Sponsor type

University/education

Website

<http://www2.warwick.ac.uk/>

ROR

<https://ror.org/01a77tt86>

Funder(s)

Funder type

Charity

Funder Name

British Orthopaedic Foundation (UK) (ref: BOF 03:07)

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?
Results article	results	05/04/2011		Yes	No