# A trial to compare operative versus nonoperative treatment of ruptures of the Achilles tendon

Submission date	Recruitment status	<ul><li>Prospectively registered</li></ul>
29/09/2006	No longer recruiting	☐ Protocol
Registration date	Overall study status	Statistical analysis plan
29/09/2006	Completed	Results
Last Edited	Condition category	Individual participant data
20/04/2015	Musculoskeletal Diseases	Record updated in last year

## Plain English summary of protocol

Not provided at time of registration

## Contact information

### Type(s)

Scientific

#### Contact name

Mr Ashvin Pimpalnerkar

#### Contact details

Good Hope Hospital NHS Trust Rectory Road Sutton Coldfield Birmingham United Kingdom B75 7RR

## Additional identifiers

**EudraCT/CTIS** number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

N0523163138

## Study information

#### Scientific Title

A trial to compare operative versus non-operative treatment of ruptures of the Achilles tendon

#### **Study objectives**

To compare operative and non-operative treatment of ruptures of the Achilles tendon.

#### Ethics approval required

Old ethics approval format

#### Ethics approval(s)

Not provided at time of registration

#### Study design

Randomised controlled trial

#### Primary study design

Interventional

#### Secondary study design

Randomised controlled trial

#### Study setting(s)

Hospital

#### Study type(s)

**Treatment** 

#### Participant information sheet

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

Musculoskeletal Diseases: Achilles tendon

#### Interventions

Arm A: operative treatment Arm B: non-operative treatment

#### Intervention Type

Procedure/Surgery

#### Primary outcome measure

Re-rupture rate and complications

#### Secondary outcome measures

Not provided at time of registration

#### Overall study start date

01/01/2005

#### Completion date

01/05/2008

## Eligibility

#### Key inclusion criteria

- 1. Complete Achilles tendon tear confirmed on ultrasound or MRI
- 2. Less than 10 days from date of injury
- 3. Aged 18 70 years old
- 4. Ability to follow rehab protocol

#### Participant type(s)

**Patient** 

#### Age group

Adult

#### Lower age limit

18 Years

#### Sex

Both

#### Target number of participants

75 patients per group

#### Key exclusion criteria

- 1. Significant ipsilateral injury
- 2. Open injury of the Achilles tendon
- 3. Neurological disease
- 4.Collagen disease
- 5. Pregnancy
- 6. Fluroquinolone associated rupture within 2 weeks of therapy
- 7. Unfit for surgery
- 8. Diabetes
- 9. Peripheral vascular disease
- 10. Avulsion of Achilles tendon

#### Date of first enrolment

01/01/2005

#### Date of final enrolment

01/05/2008

## Locations

#### Countries of recruitment

England

**United Kingdom** 

### Study participating centre Good Hope Hospital NHS Trust

Birmingham United Kingdom B75 7RR

## **Sponsor information**

#### Organisation

Record Provided by the NHSTCT Register - 2006 Update - Department of Health

#### Sponsor details

The Department of Health Richmond House 79 Whitehall London United Kingdom SW1A 2NL +44 (0)20 7307 2622 dhmail@doh.gsi.org.uk

#### Sponsor type

Government

#### Website

http://www.dh.gov.uk/Home/fs/en

## Funder(s)

#### Funder type

Government

#### **Funder Name**

Good Hope Hospital NHS Trust (UK), Own account funding

## **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