ISRCTN64598870 https://doi.org/10.1186/ISRCTN64598870

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

Submission date
29/09/2006

Recruitment status
No longer recruiting

Registration date
29/09/2006

Overall study status
Completed

Last Edited
20/04/2015

Condition category
Musculoskeletal Diseases

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

Plain English summary of protocol
Not provided at time of registration

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
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