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Acute achilles tendon rupture - minimally invasive surgery versus non-operative treatment, with immediate full weight bearing

Submission date 27/09/2006	**Recruitment status** No longer recruiting	[_] Prospectively registered [X] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 27/09/2006	**Overall study status** Completed	
Last Edited 13/09/2017	**Condition category** Musculoskeletal Diseases	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
NTR730

Study information

Scientific Title

Acute achilles tendon rupture - minimally invasive surgery versus non-operative treatment, with immediate full weight bearing: design of a randomised controlled trial

Study objectives
The study is designed to evaluate the effectiveness of conservative treatment in reducing complications when treating acute Achilles tendon rupture.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics approval received from the local medical ethics committee

Study design
Randomised controlled trial

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Acute Achilles tendon rupture

Interventions
Patients with acute Achilles tendon rupture will be randomised to minimally invasive surgical repair followed by functional rehabilitation using tape bandage or conservative treatment followed by functional rehabilitation with use of a functional bracing system.

Both treatment arms use a 7 weeks post-rupture rehabilitation protocol. Patient follow-up will be 12 month.

Intervention Type
Other

Phase
Not Specified

Primary outcome(s)
Reduction in complications other than re-rupture.

Key secondary outcome(s))
1. Re-rupturing
2. Time off work
3. Sporting activity post rupture
4. Functional outcome by Leppilahti score
5. Patient satisfaction

Completion date

01/10/2006

Eligibility

Key inclusion criteria
1. Primary spontaneous Achilles tendon rupture
2. Treatment starts within 72 hours after rupture
3. Diagnoses by physical examination: palpable gap and calf muscle squeeze test positive for tendon rupture
4. Age 18 to 65 years
5. Informed consent

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

Key exclusion criteria
1. Re-rupture/bilateral rupture/open rupture
2. Combination with fracture of foot or ankle
3. Former application (injection) of local corticosteroids in tendon area
4. Contra-indications for surgery
5. Physical or mental handicaps that do not allow functional treatment or otherwise interfere with the ability to follow-up on the study protocol

Date of first enrolment
01/02/2004

Date of final enrolment
01/10/2006

Locations

Countries of recruitment
Netherlands

Study participating centre

Diakonessenhuis
Utrecht
Netherlands
3582 KE

Sponsor information

Organisation
University Medical Center Utrecht (UMCU) (The Netherlands)

ROR
https://ror.org/0575yy874

Funder(s)

Funder type
Research organisation

Funder Name
Research foundation of Heelkunde University Medical Center Utrecht (UMCU) (The Netherlands)

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	01/09/2008		Yes	No
Protocol article	protocol	06/11/2007		Yes	No