

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

<b>Submission date</b> 27/09/2006	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
<b>Registration date</b> 27/09/2006	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 13/09/2017	<b>Condition category</b> Musculoskeletal Diseases	<input type="checkbox"/> Individual participant data

**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?
<a href="#">Results article</a>	results	01/09/2008		Yes	No
<a href="#">Protocol article</a>	protocol	06/11/2007		Yes	No