Acute Achilles tendon rupture: Minimally invasive surgery versus non operative treatment, with immediate full weight bearing. Design of a randomized controlled trial.

No registrations found.

Ethical review	Positive opinion
Status	Recruitment stopped
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON23064

Source
NTR

Brief title
N/A

Health condition

Acute Achilles tendon rupture

Sponsors and support

Primary sponsor: UMC Utrecht
Divisie Heelkunde
Source(s) of monetary or material Support: none

Intervention

Outcome measures

Primary outcome

Complications of treatment.

Secondary outcome

Time off work, sporting activity post rupture and patient satisfaction.

Study description

Background summary

Background:

We present the design of an open randomized multi-centre study on surgical versus conservative treatment of acute Achilles tendon ruptures. The study is designed to evaluate the effectiveness of conservative treatment in reducing complications when treating acute Achilles tendon rupture.<

Methods/Design:

At least 72 patients with acute Achilles tendon rupture will be randomized 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. Four hospitals in the Netherlands will participate. Primary end-point will be reduction in complications other than re-rupture, notably infection, disturbed wound healing and disturbed sensibility in the sural nerve area, adhesions and thrombosis. Secondary end-point will be re-rupturing, time off work, sporting activity post rupture and patient satisfaction. Patient follow-up will be 12 month.

Study objective

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

Study design

N/A

Intervention

Patients with acute Achilles tendon rupture will be randomized 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.

Contacts

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Eligibility criteria

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 18-65 years;

5. Informed consent.

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.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-02-2004
Enrollment:	80
Type:	Actual

Ethics review

Positive opinion

Date:	06-08-2006
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
NTR-new	NL720
NTR-old	NTR730
Other	: N/A
ISRCTN	ISRCTN50141196

Study results

Summary results
N/A