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

Gepubliceerd: 06-08-2006 Laatst bijgewerkt: 18-08-2022

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

Ethische beoordeling	Positief advies
Status	Werving gestopt
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON23064

Bron
NTR

Verkorte titel
N/A

Aandoening

Acute Achilles tendon rupture

Ondersteuning

Primaire sponsor: UMC Utrecht
Divisie Heelkunde
Overige ondersteuning: none

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Complications of treatment.

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

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

Onderzoeksopzet

N/A

Onderzoeksproduct en/of interventie

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.

Contactpersonen

Publiek

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

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.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Open / niet geblindeerd
Controle:	Geneesmiddel

Deelname

Nederland

Status:	Werving gestopt
(Verwachte) startdatum:	01-02-2004
Aantal proefpersonen:	80
Type:	Werkelijke startdatum

Ethische beoordeling

Positief advies

Datum:	06-08-2006
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

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

Resultaten

Samenvatting resultaten
N/A