Operative management of 281 Achilles tendon ruptures ;a 10 year clinical retrospective analysis

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Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Bone and joint injuries
Study type	Observational non invasive

Summary

ID

NL-OMON38370

Source
ToetsingOnline

Brief title
Achilles tendon rupture case series

Condition

- Bone and joint injuries
- Bone and joint therapeutic procedures

Synonym
achilles tendon rupture, rupture of the achilles tendon

Research involving
Human

Sponsors and support

Primary sponsor: Onze Lieve Vrouwe Gasthuis
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: achilles tendon rupture, open surgical repair, percutaneous repair, rerupture

Outcome measures

Primary outcome

Rerupure rates, complications and active range of motion of the anke of

patients surgically treated for a Achilles tendon rupture.

Secondary outcome

Patient satisfaction scores and subjective and objective function scores for

patients surgically treated for Achilles tendon rupture using the following

scoring systems: VISA-A,VAS, ATTRS, Leppilathi, SF12.

Other parameters:

The following baseline values will be collected:

- DVT

- pulmonary embolism

- fluorquinolones/steroid use

- diabetes, cardiovascular disease, smoking

- sport and level of practice

- age

- gender

- weight/height

The following injury related values will be collected:

- affected side

- pre-existent achillotendinopathie

- wound infection (superficial/deep)

- nerve damage (n.suralis)

- calf circumference

- active range of motion

- muscle strength

- time until OK

Study description

Background summary

Rupture of the Achilles tendon is one of the most common tendon injuries in the adult population.[1] In the past few decades, the incidence of Achilles tendon rupture has increased in parallel with increased sports participation.
Seventy-five percent of Achilles tendon rupture cases described in published studies are sports-related.[2]
Treatment options for acute Achilles tendon rupture include nonsurgical and surgical management. If the treating physician opts for nonsurgical treatment, the patient is treated non-operatively in a cast, cast-boot, or splint with the foot placed in plantar flexion, with or without early physiotherapy. Surgical options include open, minimally invasive, and percutaneous repair of the tendon.[3] Although the optimal treatment remains controversial[4], there is a trend towards surgical treatment in athletes.[2,5]
Various open an minimally-invasive surgical techniques have been described, but there is no consensus as to which technique has the best results regarding incidence of rerupture, sural nerve injury and strength.[6]

The objective of this study is to assess the rerupture rate, Achilles tendon function and patient satisfaction after treatment of a Achilles tendon rupture with a open surgical reconstruction or a percutaneous reconstruction of the Achilles tendon.

Study objective

We think that the results of this study could be the start of other studies and eventually lead to international standards for treatment of Achilles tendon

ruptures.

Study design

Retrospective case series study. Patients will be asked to fill out forms (VISA-A, VAS, ATTRS,SF12). Physical examination will be performed in the OLVG by the examinator in order to complete the Leppilathi score

Study burden and risks

Patients will have to visit the OLVG hospital one time for physical examination (aprox. 20 minutes). Expence allowance will be offered. Patients will also be asked to fill out four questionnaires by them selves at home (aprox. 20 minutes). There are no risks associated with participation.
Burden en risk are nill, therefore this research is justified.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age

Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

Patients treated in the period 2002-2012 for a complete rupture of the achilles tendon at the OLVG.
Age : 18-65 Years
Treatment initiated <72h after rupture
Diagnosis through palpable gap and positive Thompson test
Informed consent

Exclusion criteria

- rerupture/ bilateral rupture/ open rupture
- combination of rupture with a fracture of the foot/ankle
- previous treatment with local anestethics
- fysical/mental handicaps that may possibly interfer with follow-up
- APR treated with conservative treatement

Study design

Design

Study type: Observational non invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	12-02-2014
Enrollment:	281
Type:	Actual

Ethics review

Approved WMO Date:	29-01-2014
Application type:	First submission
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)

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
CCMO	NL47098.100.13