

# The difference in maximal dorsoflexion angle of the ankle when performing the weight bearing dorsoflexion lunge test in patients with a chronic midportion Achilles tendinopathy and healthy controls: A cross-sectional study.

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The objective of this study is to determine the difference in maximal dorsoflexion angle of the ankle when performing the weight bearing dorsoflexion lunge test between patients with a chronic midportion Achilles tendinopathy and healthy controls.

<b>Ethical review</b>	Approved WMO
<b>Status</b>	Recruitment stopped
<b>Health condition type</b>	Tendon, ligament and cartilage disorders
<b>Study type</b>	Observational non invasive

## Summary

### ID

NL-OMON47509

### Source

ToetsingOnline

### Brief title

Dorsoflexion lunge study

### Condition

- Tendon, ligament and cartilage disorders

### Synonym

Achilles tendinopathy, overuse injury Achilles tendon

### Research involving

Human

## Sponsors and support

**Primary sponsor:** Haaglanden Medisch Centrum

**Source(s) of monetary or material Support:** Reumafonds en Annafonds

## Intervention

**Keyword:** Achilles, Risk factor, Tendinopathy

## Outcome measures

### Primary outcome

The primary outcome is the difference in the maximal dorsoflexion angle of the ankle when performing the weight bearing dorsoflexion lunge test between patients with a chronic midportion Achilles tendinopathy and healthy controls.

### Secondary outcome

Secondary outcomes are the difference in strength of the gastrocnemius and soleus muscle, flexibility of the gastrocnemius and soleus muscle when performing an one leg jump and and quantification of the neovascularisations using ultrasound between patients with a chronic midportion Achilles tendinopathy and healthy controls.

## Study description

### Background summary

Overuse injury of the midportion of the Achilles tendon is a common entity in athletes and sedentary persons. As an example, Elite running athletes have a lifetime risk of sustaining an Achilles tendon injury of 52%. The diagnosis is made when the classic triad is present: local tenderness, local swelling and a decreased weight bearing capacity.

The pathogenesis of an Achilles tendinopathy is degeneration of collagen fibers

and neovascularization. Chronic tendon overload is considered to be the main reason for developing an Achilles tendinopathy. Several other risk factors for developing Achilles tendinopathy have been proposed, such as a reduced dorsiflexion of the ankle, obesity, excessive pronation of the foot, decreased mobility of the subtalar joint and a decreased flexibility and force of the gastrocnemius-soleus complex. The reduced dorsiflexion of the ankle could potentially be used to advise the performance of stretching exercises of the calf. At this moment however, scientific evidence for the difference between patients and healthy controls is scarce.

### **Study objective**

The objective of this study is to determine the difference in maximal dorsoflexion angle of the ankle when performing the weight bearing dorsoflexion lunge test between patients with a chronic midportion Achilles tendinopathy and healthy controls.

### **Study design**

This study has a cross-sectional study design. Healthy control will be compared with patients who are included in the double- blind, placebo-controlled intervention study which is in progress (HAT study).

### **Study burden and risks**

The burden due to participation will be 45 minutes in a single visit. During this visit, clinical tests as described above will be performed and a questionnaire will be carried out. Therefore, the burden due to participation is expected to be minor.

## **Contacts**

### **Public**

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## Trial sites

### Listed location countries

Netherlands

## Eligibility criteria

### Age

Adults (18-64 years)

Elderly (65 years and older)

### Inclusion criteria

- Age 18-70 years.
- Absence of clinical diagnosis of chronic midportion Achilles tendinopathy: Painfull swelling of the Achilles tendon, 2-7 cm proximal to it\*s calcaneal insertion.

### Exclusion criteria

- Known to have the following disorders: spondylarthropathy, gout, hyperlipidemia, rheumatoid arthritis and sarcoïdosis.
- Inability to perform a heavy load eccentric exercise program
- Recently prescribed drugs (within 2 months) with a putative effect on symptoms and tendon healing (quinolone antibiotics, corticosteroids)
- Presence of pregnancy
- Previous Achilles tendon rupture
- A medical condition that would affect safety of an injection (e.g. peripheral vascular disease, use of anticoagulant medication)
- Inability to give informed consent
- Participation in other concomitant treatment programs
- Participant has already one side included in this study

## Study design

### Design

**Study type:** Observational non invasive

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

## Recruitment

NL	
Recruitment status:	Recruitment stopped
Start date (anticipated):	10-07-2019
Enrollment:	29
Type:	Actual

## Ethics review

Approved WMO	
Date:	12-01-2018
Application type:	First submission
Review commission:	METC Leiden-Den Haag-Delft (Leiden)
	metc-ldd@lumc.nl

Approved WMO	
Date:	22-02-2019
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden)
	metc-ldd@lumc.nl

## 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

CCMO

### ID

NL61465.098.17