The value of a High-Volume Image-Guided Injection in chronic midportion Achilles tendinopathy: a double-blind, placebo-controlled, randomised clinical trial

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Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Tendon, ligament and cartilage disorders
Study type	Interventional

Summary

ID

NL-OMON47722

Source
ToetsingOnline

Brief title
HAT-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: Subsidieaanvraag gehonoreerd door Reumafonds en Annafonds (gezamenlijke financiering)

Intervention

Keyword: Achilles, Injection, Tendinopathy, Treatment

Outcome measures

Primary outcome

Our primary outcome measurement is the VISA-A score. This measures pain,

function and activity level. It is validated en reliable for the chronic

Achilles tendinopathy.

Secondary outcome

Our secundary outcome measurements are as follows:

- The painDETECT questionnaire.

- The Pain Coping Inventory (PCI) questionnaire

- Subjective function of the Achilles tendon (5-point Likert scale) and

subjective recovery (7-point Patient's Global Assessment scale)

- Physical examination: waist circumference, length, weight, foot posture

index, palpation pain (VAS 0-100), flexibility and strength gastrocnemius and

soleus muscle, jumping height (cm) and pain during jump test (VAS 0-100) and 10

times hopping (VAS 0-100, part of the VISA-A questionnaire) (First 66 patients)

- Degree of neovascularisation (determined with standarised Power Doppler

Ultrasonography examination) before and after eccentric/isotonic calf exercises

or rest (First 66 patients)

- Subjective patient satisfaction (excellent / good / fair / poor)

- Return to sports (Return to desired sport on pre-injury level / return to

desired sport but on a lower level / return to sports but not desired sport /

no return to sports)

- Time to return to full training in desired sport.

- Compliance to the exercise programme and return to sports activity programme

(RPE score x duration of activity)

Study description

Background summary

Overuse injury of the Achilles tendon is a common entity in athletes. Especially middle aged athletes are at risk. Elite running athletes have a lifetime risk of sustaining an Achilles tendon injury of 52%. At the moment the usual treatment for chronic midportion Achilles tendinopathy is an excentric exercise programme. In most cases this gives great results, however there is a significant group of patients in which the exercise programme is not sufficient.
Prior to our study, three UK based studies have investigated the efficiancy of High-Volume Image-Guided Injections (HVIGI*s) in chronic midportion Achilles tendinopathy. They all showed promising results. However none of these studies had a placebo group. Because of this, these investigations do not help in giving advise on which treatment option to use in chronic midportion Achilles tendinopathy.

Study objective

Our objective is to investigate the value of a HVIGI in chronic midportion Achilles tendinopathy, using a dubbel-blind, placebo-controlled, randomised clinical trial. We expect that this study design gives us the opportunity to provide solid advise on how to treat this chronic injury.

Study design

A computer-generated randomisation will lead into two groups of patients:

1. High-Volume Image-Guided Injection (HVIGI) * 50ml (0,9% NaCl solution + 1% lidocaïne) in combination with an exercise programme and gradual return to sports activities.

2. Low-Volume Image-Guided Injection (LVIGI) * 2ml (0,9% NaCl solution + 1% lidocaïne) in combination with an programme and gradual return to sports activities.

There are five measurement points. These measurement points are at 0, 2, 6, 12 and 24 weeks post treatment. Every time both the primairy and secondary outcome measurements are collected.

Intervention

Both groups receive an injection anterior to the Achilles tendon on the medial side. The sports physician injects a mixture of 0,9% saline solution and lidocaïne in the peritendinous space of the Achilles tendon. The sports physician determines the amount of neovascularisation with a power-doppler ultrasonography (PDU) while injecting the solution. When the sports physician has injected 50ml, he stops injecting. In the intervention group, there is 10ml of lidocaïne processed in the mixture. The placebo group receives 2ml of the solution, of which is 0,4ml lidocaïne. Both procedures take the same amount of time and are carried out equally. At the end of the procedure, the patiënt lies prone on the investigation table for 5 minutes.

Study burden and risks

The exercise programme consists of 12 weeks exercise therapy. The exercises are performed daily and start with isometric exercises, followed by concentric, eccentric and plymetric exercises. The estimated time consumed by the exercises is less than 15 minutes daily. The exercises can be painful, but this will only be bothersome in the beginning.
In previous studies with HVIGI*s, no complications have been described. Even though an anestheticum is mixed through the mixture, the initial treatment can be painful. This pain will go away soon after treatment.|

During the investigation the patient visits the hospital five times. The first appointment takes approximately 110 minutes. The second, third, fourth and fifth will only takes 40 minutes. The complete follow-up will be 24 weeks.

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

- Age 18-70 years.
- Clinical diagnosis of chronic midportion Achilles tendinopathy: Painfull swelling of the Achilles tendon, 2-7 cm proximal to it*s calcaneal insertion.
- Non-response to excercise program for 6 weeks.
- Painfull Achilles tendon for more than 2 months.
- Neovascularisation is present on Power Doppler Ultrasonography examination

Exclusion criteria

- Clinical suspicion of insertional disorders.
- Clinical suspicion of Achilles tendon rupture.
- Clinical suspicion of plantar flexor tenosynovitis.
- Clinical suspicion of peroneal tendinopathy or subluxation.
- Clicical suspicion of sural nerve pathology.
- Condition of the Achilles tendon caused by medication, such as quinolones and statins.
- 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 years) with a putative effect on symptoms and tendon healing (quinolone antibiotics, corticosteroids).

- Presence of pregancy.
- Previous Achilles tendon rupture.
- Patient has received surgical intervention for his injury.
- A medical condition that would affect safety of injection (e.g. peripheral vascular disease, use of anticoagulant medication)
- Inability to give informed consent.
- Participation in other concomitant treatment programs.
- Patient has already one side included in this study.
- Patient does not wish, for whatever reason, to undergo one of the two treatments.
- Allergy for lidocain.

Study design

Design

Study phase:	4
Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Placebo
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	21-12-2016
Enrollment:	84
Type:	Actual

Medical products/devices used

Product type:	Medicine
Brand name:	Lidocaine
Generic name:	Lidocaine
Registration:	Yes - NL intended use
Product type:	Medicine

Brand name:	Sodium Chloride
Generic name:	Sodium Chloride
Registration:	Yes - NL intended use

Ethics review

Approved WMO Date:	05-03-2015
Application type:	First submission
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

Approved WMO Date:	22-04-2015
Application type:	First submission
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

Approved WMO Date:	17-05-2016
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

Approved WMO Date:	14-10-2016
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

Approved WMO Date:	28-10-2016
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

Approved WMO Date:	30-07-2018
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

Approved WMO Date:	16-11-2018
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

Approved WMO Date:	04-02-2019
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	ID
EudraCT	EUCTR2015-000180-13-NL
CCMO	NL51623.098.15
Other	NTR: 4916