High-Volume Image-Guided Injection in chronic midportion Achilles tendinopathy

No registrations found.

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

Summary

ID

NL-OMON25970

Source
Nationaal Trial Register

Brief title
HAT-study

Health condition

Achilles tendon
Tendinopathy
Injection
Treatment
High-Volume

Achillespees
Tendinopathie
Injectie
Behandeling
Hoog-Volume

Sponsors and support

Primary sponsor: Erasmus University Medical Centre, department of orthopaedics. Collaboration with Haaglanden Medical Centre, department of sports medicine.
Source(s) of monetary or material Support: ReumaNederland and Annafonds

Intervention

Outcome measures

Primary outcome

The Victorian Institute of Sports Assessment-Achilles (VISA-A) score. This is a validated, reliable and disease-specific questionnaire to evaluate symptoms in patients with chronic midportion Achilles tendinopathy

Secondary outcome

- PainDETECT questionnaire

- Pain Coping Inventory (PCI) questionnaire

- 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)

- Degree of neovascularization (determined with

standardized Power Doppler Ultrasonography examination)

- 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)

- Compliance to the exercise program.

Study description

Background summary

Background of the study

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 program. In most cases this gives great results, however there is a significant group of patients in which the exercise program is not sufficient.
Three UK-based case series evaluated the efficacy of High-Volume Image-Guided Injections (HVIGI's) in chronic midportion Achilles tendinopathy. They all showed promising results. However none of these studies used a comparative group. There is consequently a lack of high-quality studies in this field and therefore we cannot recommend this treatment yet for this indication.

Objective of the study

To investigate the efficacy of a high-volume image guided injection (HVIGI) in chronic midportion Achilles tendinopathy.

Study design

A double-blind, placebo-controlled, randomized controlled

trial. Randomization and stratification (based on activity level using the Ankle Activity Score) will be performed using a computer-generated model. Measurements will be performed at baseline, 2, 6, 12 and 24 weeks post injection. At every time point both the primary and secondary outcome measurements will be collected. The painDETECT and the Pain Coping Inventory questionnaires will be derived at baseline and 24 week post injection.

Study population

In total, 80 patients with clinically diagnosed chronic midportion Achilles tendinopathy will be included in this study.

Intervention

Patients will be randomized into one of the two treatment groups:

1. High-Volume Image-Guided Injection (HVIGI) – 50ml (0.9% NaCl solution + 1% lidocaine) in combination with an isometric/eccentric exercise program and a return to sports program.

2. Low-Volume Image-Guided Injection (LVIGI) – 2ml (0.9% NaCl solution + 1% lidocaine) in combination with an eccentric exercise program. The sports physician performs the injection in the peritendinous space of the Achilles

tendon and the amount of neovascularization is determined with a power-doppler ultrasonography (PDU) before and after this procedure. In the intervention group, there is 10ml of lidocaine processed in the mixture. The placebo group receives 2ml of the solution, of which is 0.4ml lidocaine. Both procedures take the same amount of time and are carried out equally. At the end of the procedure, the patient lies prone on the investigation table for 5 minutes.

Primary study parameters/outcome of the study

- VISA-A score. This measures pain, function and activity level. It is validated and reliable for the chronic Achilles tendinopathy.

Secondary study parameters/outcome of the study

- PainDETECT questionnaire
- Pain Coping Inventory (PCI) questionnaire
- 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)
- Degree of neovascularization (determined with standardized Power Doppler Ultrasonography examination)
- 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)

- Compliance to the exercise program.

Study objective

High-Volume Image-Guided injections will provide a significant improvement in symptoms compared to Low-Volume Image-Guided injections in patients suffering from chronic midportion Achilles tendinopathy

Study design

Baseline, 2, 6, 12 and 24 weeks

Intervention

High-Volume Image-Guided Injection (50 ml) in the peritendinous space of the Achilles tendon

Contacts

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Eligibility criteria

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 eccentric excercise program for 6 weeks.

- Painfull Achilles tendon for more than 2 months.

- Neovascularization is present using 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.

- Clinical 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 pregnancy.

- 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.

Study design

Design

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-11-2016
Enrollment:	80
Type:	Actual

IPD sharing statement

Plan to share IPD: Undecided

Ethics review

Positive opinion

Date:	19-11-2014

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	NL4686
NTR-old	NTR4916
Other	METC ZWH : 14 - 100

Study results