Does extracorporal shockwave therapy result in short term improvement of tendon structure in symptomatic midportion Achilles tendinopathy? An ultrasound tissue characterisation study

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This research is part of the evaluation of regular care.Primary objective:(1) to investigate whether 4 weekly shockwave treatments for soldiers with mid-portion Achilles tendon endopathy result in an improvement in Achilles tendon structure after 8...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Other condition
Study type	Interventional

Summary

ID

NL-OMON49833

Source
ToetsingOnline

Brief title
Does shockwave treatment improve Achilles tendon structure?

Condition

- Other condition
- Tendon, ligament and cartilage disorders

Synonym
Achilles tendon pain, Tendinopathy

Health condition

(Achillespees) tendinopathieën

Research involving
Human

Sponsors and support

Primary sponsor: Koninklijke Landmacht
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Achilles tendon, Shockwave therapy, Tendinopathy, Ultrasound tissue characterization

Outcome measures

Primary outcome

(1) The primary outcome measure is the quantitative improvement / change of

Achilles tendon structure.

This is objectified with Ultrasound Tissue Characterization (UTC).

UTC is a variant of ultrasound, in which a validated algorithm analyzes the

three-dimensional stability of the echo pattern over several, successive, axial

grayscale images. The echotypes vary from organized matrix (echotypes I and II)

to disorganized matrix (echotypes III and IV):

- Echotype I: (green colored) very stable; intact and aligned tendon bundles

- Echotype II: (blue colored) moderately stable: discontinuous or more wavy

tendon bundles

- Echotype III: (red colored) high variability: fibrilar matrix

- Echotype IV: (black colored) constant low intensity and variable

distribution: complete disintegration of the matrix; amorphous tissue and fluid.

Secondary outcome

(2) Pain is expressed in a numeric rating scale (NRS), 0: "no pain" - 10: "worst pain ever".

(3) The severity of the mid-portion Achilles tendinopathy is objectified with the VISA-A questionnaire (results range from 0-100, where 100 equals a perfect asymptomatic score (Robinson et al., 2001).

(4) The patient's opinion on recovery is made clear with the help of the Global Experienced Effect Score (GEE, 0: "much better" - 7: "very much worse") (Hudak & Wright, 2000).

Study description

Background summary

Trainingsgeneeskunde & Trainingsfysiologie (TGTF) is the sports medical center of the Royal Netherlands Army. With TGTF, shockwave treatment is part of the regular care for soldiers who are referred with mid-portion Achilles tendinopathy.

Mid-portion Achilles tendinopathy is a painful condition that occurs frequently in physically highly active populations, including soldiers and athletes. The condition is characterized morphologically mainly by tendon degeneration, and can result in significant limitations in sport and employability. Shockwave treatment has been shown to be effective for treating pain and function in various chronic tendinopathies. Results from in vitro and in vivo studies suggest that shockwave treatment promotes the regenerative properties of tendinopathic Achilles tendons.
As far as we know, this phenomenon has not been quantitatively investigated in a clinical setting.
We hypothesize that shockwave treatment improves the tendon structure of the mid-portion of the Achilles tendons.

Study objective

This research is part of the evaluation of regular care.

Primary objective:
(1) to investigate whether 4 weekly shockwave treatments for soldiers with mid-portion Achilles tendon endopathy result in an improvement in Achilles tendon structure after 8 and 26 weeks.

Secondary objectives:
We also try to evaluate the effects of shock wave treatment on:
(2) pain
(3) the severity of the mid-portion Achilles tendonopathy
(4) the patient's opinion about the recovery

Study design

This is a prospective cohort study.

Intervention

Shockwave treatment is a non-invasive treatment method that is effective for treating pain and improving function in mid-portion Achilles tendinopathy. The subjects are treated with shockwave a total of four times for four consecutive weeks. 2000 shocks are distributed per treatment over the painful area of the mid-portion of the affected Achilles tendon. Studies indicate that the effectiveness of shockwave therapy appears to be dependent on intensity, with the highest possible intensity appearing more effective in treating mid-portion Achilles tendinopathy.
In this study, after the start of treatment, the intensity is quickly increased to an intensity that the subject can tolerate during the treatment period of approximately 4 minutes.

Study burden and risks

The risks of both diagnosis and intervention are minimal.
In addition to short-term redness of the skin, no adverse reactions have been reported in the literature from shockwave treatment for mid-portion Achilles tendinopathy.
Making a UTC scan is also safe. UTC falls under ultrasound imaging, making no use of ionizing radiation. There is therefore no radiation tax (RIVM) either.

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

Inclusion criteria:
1. mid-portion Achilles tendon pain for more than two months, whereby the complaints are of such a nature that a doctor is visited due to pain or functional discomfort
2. active military personnel

Exclusion criteria

Exclusion criteria:
1. prior Achilles tendon surgery
2. insertional (in stead of mid-portion related) symptoms

3. signs of a Complete Achilles tendon rupture
4. use of specific medications: statins, fluorquinolones or corticosteroids
5. individuals suffering from specific diseases: rheumatoid arthritis, diabetes mellitus, psoriasis

Study design

Design

Study type: Interventional

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	09-07-2019
Enrollment:	40
Type:	Actual

Medical products/devices used

Generic name:	Ultrasound Tissue Characterisation
Registration:	Yes - CE intended use

Ethics review

Approved WMO Date:	08-07-2019
Application type:	First submission
Review commission:	METC Brabant (Tilburg)
Approved WMO Date:	20-10-2020
Application type:	Amendment
Review commission:	METC Brabant (Tilburg)

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	NL69527.028.19