Effectiveness of eccentric calf muscle exercise therapy in patients with chronic midportion Achilles tendinopathy.

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To evaluate the effectiveness of eccentric calf muscle exercise therapy compared to strength training of the upper extremities (control group) in patients with chronic midportion Achilles tendinopathy.

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

Summary

ID

NL-OMON46182

Source
ToetsingOnline

Brief title
EXPAT

Condition

- Tendon, ligament and cartilage disorders

Synonym
Achilles overuse, Achilles tendinopathy

Research involving
Human

Sponsors and support

Primary sponsor: Isala Klinieken
Source(s) of monetary or material Support: Isala ziekenhuis

Intervention

Keyword: Achilles tendinopathy, eccentric exercise therapy, midportion

Outcome measures

Primary outcome

Primary outcome is the validated and disease-specific Victorian Institute of

Sports Assessment-Achilles (VISA-A) questionnaire after 12 weeks.

Secondary outcome

Pain during functional tests

Pain during activities of daily living

Pain during sports

Patient satisfaction

Return to sport

Adherence to the exercise therapy protocol

adherence of the exercise program and return to pre-injury sports activities.

Study description

Background summary

Both in athletes and inactive individuals, chronic midportion Achilles tendinopathy is a common problem, and limits patients in sports and daily activities. Chronic midportion Achilles tendinopathy is characterized by structural disorganization of the tendon collagen that alters the loading capacity. According to the current Dutch multidisciplinary guideline, painful eccentric calf muscle exercise therapy is recommended as first treatment of choice with the aim to decrease pain, restore function and tendon structure on the longer term. A recent systematic review showed, however, that other forms of calf muscle exercise therapy are equal to eccentric exercises for this patient group. It is, however, unknown whether these painful calf muscle exercises are more effective than strengthening exercises that are not related to the affected musculotendinous unit. There are currently no studies with a

proper control group to answer this research question. An adequate and innovative study design is needed to determine whether painful calf muscle exercises are necessary for this patient group. The hypothesis is that eccentric calf muscle exercise therapy (usual care) is more effective than exercise therapy of the upper extremities.

Study objective

To evaluate the effectiveness of eccentric calf muscle exercise therapy compared to strength training of the upper extremities (control group) in patients with chronic midportion Achilles tendinopathy.

Study design

Single-blind, prospective, randomized controlled, single center trial. The study will be performed at the Sports Medicine Department, Isala hospital Zwolle, the Netherlands.

Intervention

One group will be instructed to perform a daily home-based 12-week heavy load eccentric calf muscle exercise program. The other group will be instructed to perform a daily home-based 12- week heavy load exercise program for the upper extremities. Both groups will receive advices for load management according to the pain-monitoring model, which is also part of the current usual care.

Study burden and risks

The burden of participation consists of completing a total of two hospital visits for inclusion at baseline and follow-up at 12 weeks. Additionally, patients will complete an online questionnaire at three additional time points. Adherence to the exercise protocol will be asked on a weekly basis using a short digital questionnaire during 12 weeks of treatment.
Hospital visits will not result in healthcare costs for the patient.
No drugs will be administered in the context of this study.
No adverse events are to be expected resulting from both exercise regimens under evaluation. Both exercise therapies are safe and currently being used as usual care for chronic midportion Achilles tendinopathy and shoulder injuries. Therefore, the burden and risks for patients participating are limited

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

Pain on palpation 2-7 cm above the insertion of the Achilles tendon (*midportion*)
Achilles tendon symptoms for at least 2 months
Age 18-70 years

Exclusion criteria

Clinical suspicion of other disorders as insertional disorders, Achilles tendon rupture, plantar flexor tenosynovitis, sural nerve pathology, peroneal subluxation
History of Achilles tendon rupture on the affected side, spondylarthropathy, gout, familial hypercholesterolemia and rheumatoid arthritis
Patient has received an injection or surgical intervention for this injury, or already performed eccentric calf muscle exercises for >=4 weeks with a complete adherence to the protocol or a comparable absolute number of exercise sets (n = 5040) in the previous year
Presence of pregnancy
Patient is nog able or does not wish to participate

Study design

Design

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	08-08-2019
Enrollment:	68
Type:	Actual

Ethics review

Approved WMO Date:	10-01-2019
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)

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	NL67061.075.18