The effect of an isometric plus eccentric-concentric exercise protocol compared to the usual care eccentric exercise protocol on Achilles tendon pain and structure in subjects diagnosed with Insertional Achilles tendinopathy - A pilot study

Published: 07-04-2017
Last updated: 14-04-2024

The primary objective of this pilot study is to determine the effect of an isometric exercises plus eccentric-concentric exercise protocol compared to the usual care eccentric exercise protocol on Achilles tendon pain and structure in subjects...

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

Summary

ID

NL-OMON45302

Source
ToetsingOnline

Brief title
IAT study

Condition

- Tendon, ligament and cartilage disorders

Synonym
achillodynia, tendon overuse injury

Research involving

Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Groningen
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Achilles, exercise, tendinopathy

Outcome measures

Primary outcome

- Pain on VAS during the calf-raise test in patients with IAT.

Secondary outcome

- Tendon structure;

- Pain during different tasks (eg. rest, daily activity);

- Function (VISA-A);

- Quality of life (SF-36);

- Impact on work (QQq and single WAI);

- Patient impression of improvement (6-point Likert scale)

Study description

Background summary

The Achilles tendinopathy (AT) is a clinical syndrome characterized by a combination of pain and swelling in and around the Achilles tendon, accompanied by impaired performance. This overuse tendon injury is common among sport-active population, especially runners, but can also affect patients who do not participate in sports. The incidence of AT in running athletes has been estimated between 11% and 29%. On the non-sport population, Kujala UM et al describe the incidence of 6%.
The Achilles tendinopathy can be classified as insertional, symptoms that occur at the bone-tendon junction or as non-insertional, those that occur more

proximally. In the present study, the IAT will be the focus.
Eccentric exercises programme has been show to be successful for patients with noninsertional AT, improving the VISA-A score and pain. But the results for IAT are still unclear. There is no isometric exercise combined with eccentric-concentric exercise described in the literature specifically for AT.
But a preview research with lateral elbow tendinopathy, which normally occurs on the proximal portion of the tendon (similar to the IAT), observed a decrease in pain score and an improvement of function.

Study objective

The primary objective of this pilot study is to determine the effect of an isometric exercises plus eccentric-concentric exercise protocol compared to the usual care eccentric exercise protocol on Achilles tendon pain and structure in subjects diagnosed with insertional Achilles Tendinopathy.

Study design

Randomized controlled trial (pilot study)

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

1. Isometric exercise plus eccentric-concentric exercise.
2. Eccentric exercise.

There are four measurement points: 0, 4, 8 and 12 weeks.

Intervention

Group 1:
- Isometric exercise + eccentric-concentric exercise
To perform the isometric exercise program, patient will be instructed to standing with all body weight on the forefoot and the ankle joint in plantar flexion during 45 seconds. Patients will perform 5 repetitions each time and the load will be increased as the same of eccentric group. After the four weeks, all patients will be instructed to perform the eccentric-concentric exercise until the twelfth week. The eccentric-concentric exercise is similar to the eccentric exercise performed by the eccentric group, but pacients will perform the concentric phase with the injured leg.

Group 2:
- Eccentric exercise
The protocol will be performed 2 times daily, 7 days/week, during 12 weeks. Patient will begin the exercise from an upright body position and standing with all body weight on the forefoot and the ankle joint in plantar flexion, the

calf muscle will be loaded by having the patient lower the heel until the floor level.

Study burden and risks

Risks: No long-term risk known
Burden: Participation in the study will require two extra visits to UMCG for the UTC and SWE scans and completion of questionnaires and the VAS pain scale.

Contacts

Public
Universitair Medisch Centrum Groningen

Hanzeplein 1
Groningen 9700RB
NL
Scientific
Universitair Medisch Centrum Groningen

Hanzeplein 1
Groningen 9700RB
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

Age 18 - 55 years

Pain on palpation in the distal part of the tendon (insertion)
Symptoms > 3 months
Sign the written informed consent

Exclusion criteria

Midportion Achilles tendinopathy
Achilles tendon rupture
Suspicion of a systematic disease
Previous injections for the same injury

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	19-04-2017
Enrollment:	30
Type:	Actual

Ethics review

Approved WMO

Date:	07-04-2017
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	NL58748.042.16