The value of Autologous Tenocyte Implantation in patients with chronic Achilles tendinopathy: a double-blind randomised clinical trial

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This study is designed to compare the treatment of 2 groups: autologous tenocytes injection in combination with exercises versus saline injection in combination with exercises.

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

Summary

ID

NL-OMON38070

Source
ToetsingOnline

Brief title
ATI in Achilles tendinopathy

Condition

- Tendon, ligament and cartilage disorders

Synonym
Achillodynia, tendon overuse injury

Research involving
Human

Sponsors and support

Primary sponsor: Erasmus MC orthopaedic department
Source(s) of monetary or material Support: Ministerie van OC&W,Orthocell

Intervention

Keyword: Achilles, cell therapy, eccentric exercises, tendinopathy

Outcome measures

Primary outcome

Primary outcome measurement: VISA-A score, a validated instrument to detect the severity of symptoms in patients with Achilles tendinopathy.

Secondary outcome

As secondary outcome measurements subjective patient satisfaction and return to sports will be rated. For the evaluation of tendon repair, Ultrasonographic Tissue Characterization (UTC) will be performed. UTC was developed, that provides quantitative information on tendon fiber alignment and the related ultra-structural integrity of the tendon tissue through a non-invasive approach and is used in several clinical trials in humans.

Study description

Background summary

Overuse injury of the Achilles tendon is a common entity. When the exact origin of tendon pain is unclear, the term tendinopathy is preferred. Most accepted treatment at this moment is an eccentric exercise programme, according to the Dutch guidelines. However, a recent systematic review on the effectiveness of eccentric exercises to treat lower extremity tendinoses concluded that it is unclear whether eccentric exercises are more effective than other forms of treatment. Recent studies described new treatment strategies in tendinopathies, such as the use autologous Tenocyte Implantation (ATI). This treatment option can participate actively in tissue repair processes on cell level.
The only published clinical pilot study in tendon research reported 60% improvement in all scores after 6 months follow-up.

Study objective

This study is designed to compare the treatment of 2 groups: autologous tenocytes injection in combination with exercises versus saline injection in combination with exercises.

Study design

The study will be a double-blind randomised single-centre clinical trial comparing 2 treatment groups. The researcher, the sports medicine physician and the patients will be blinded to the received therapy.

Intervention

All patients will perform a heavy load eccentric exercise programme, consisting of 180 repetitions daily. The patients will be randomized into 2 treatment groups: ultrasound guided intratendinous saline injection with eccentric exercises and ultrasound guided intratendinous ATI (autologous tenocyte implantation) injection with eccentric exercises.

Study burden and risks

The intratendinous injections may be painful and a hematoma can arise. In previous (animal) studies on the effect of autologous tenocyte implantation on tendon disorders at other locations, it was reported that no tendon ruptures occured. However, we are not sure whether these results could be extrapolated to the Achilles tendon. A pilot study in patients with tennis elbow did not show this technique to be unsafe. The eccentric exercises are frequently painful and it requires discipline. Moreover, there are 3 follow-up moments and 1 follow-up by phone for the patients after injection (with the duration of 30 minutes per appointment).

Contacts

Public
Erasmus MC orthopaedic department

Dr Molewaterplein 50
Rotterdam 3015GE
NL
Scientific
Erasmus MC orthopaedic department

Dr Molewaterplein 50
Rotterdam 3015GE
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

1. Pain on palpation 2-7 cm proximal from the tendon insertion ("midportion")
2. Symptoms > 2 months
3. Age 18-55 years

Exclusion criteria

- Clinical suspicion of insertional disorders , Achilles tendon rupture, plantar flexor tenosynovitis, sural nerve pathology, peroneal subluxation
- Condition of the Achilles tendon caused by medications such as quinolones and statins
- Known to have the following disorders: spondylarthropathy, gout, hyperlipidemia, rheumatoid arthritis and sarcoidosis.
- Antibiotics allergy (aminoglycoside group)
- A condition that prevents the patients from executing an active rehabilitation programme
- Patient has received an injection for this injury
- Patient has received surgical intervention for this injury
- Patient has already one site (left or right) included in this study
- Patient does not wish, for whatever reason, to undergo one of the two treatments
- Known pregnancy
- Nursing women

Study design

Design

Study phase:	2
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):	29-04-2011
Enrollment:	90
Type:	Actual

Medical products/devices used

Product type:	Medicine
Generic name:	Somatic cells autologous

Ethics review

Approved WMO Date:	02-08-2010
Application type:	First submission
Review commission:	CCMO: Centrale Commissie Mensgebonden Onderzoek (Den Haag)
Approved WMO Date:	25-01-2011
Application type:	First submission
Review commission:	CCMO: Centrale Commissie Mensgebonden Onderzoek (Den Haag)
Approved WMO Date:	15-08-2011
Application type:	Amendment

Review commission:	CCMO: Centrale Commissie Mensgebonden Onderzoek (Den Haag)
Approved WMO Date:	12-03-2013
Application type:	Amendment
Review commission:	CCMO: Centrale Commissie Mensgebonden Onderzoek (Den Haag)

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	EUCTR2010-021869-73-NL
CCMO	NL33178.000.10