

# A randomised controlled study; treatment of patellatendinopathy with excentric exercise and shockwavetherapy

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The purpose of the study is compare the effect excentric exercise in combination with electric shockwave therapy with excentric exercise and sham shockwave therapy. This is measured with the VISA-P score in short term, middle term and long term...

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

## Summary

### ID

NL-OMON39083

### Source

ToetsingOnline

### Brief title

treatment of patellatendinopathy

### Condition

- Tendon, ligament and cartilage disorders

### Synonym

pain of the tendon of the knee.

### Research involving

Human

### Sponsors and support

**Primary sponsor:** Medisch Centrum Haaglanden

**Source(s) of monetary or material Support:** MCH en fysiotherapiepraktijk Rayer healthcare

## Intervention

**Keyword:** excentric exercise, patellatendinopathy, RCT, shockwave

## Outcome measures

### Primary outcome

VISA-P: Victorian Institute of Sport Assessment: This validated score evaluates pain, function and sportspractice. A score of 100 gives an optimal knee without symptoms (Zwerver 2009). When there is pain in both knees than the score is for the most painful side.

### Secondary outcome

Pain pressure threshold: The pain pressure threshold is determined by a dolorimetre on the most painful part of the patellatendon. In this position the dolorimetre is read off a qauntity of Newton.

VAS: Visual Analogue scale for pain: patient gives a number on a scale from 0-10 whereas 0= no pain and 10= terrible pain. We take this score after 10 times on a declineboard of 25 degrees, the triple hop test and the maximal jump test (Zwerver 2010)

Likert score: functional score of improvement of symptoms.

## Study description

### Background summary

Tendinopathy of the patellatendon, jumper's knee, is a chronic overuse injury of the patella tendon. It can result in ending the sportcareer. There is pain in the inferior part of the patella tendon, which increases with

more stress. When there is a chronic tendinopathy there is a disrupted regeneration process. Because of that shock absorption is less than normal. Tendinopathy of the patella tendon can be treated with eccentric exercise. This treatment was first described by Curwin and Stanish in 1984. The best results are described when squats are done in an angle of 25 degrees. The painful leg makes a flexion of the knee, after that with both legs up. Each day two sessions of three sets of fifteen repetitions. With this treatment 50-70% of the patients improve in knee function and pain.

Except eccentric exercise there is another treatment started in the '90s, extracorporeal shockwave therapy (ESWT). Wang found in 2007 a significant improvement of pain, VISA-P and knee function. Van Leeuwen et al concluded in 2009 that ESWT is an effective and safe way for treatment in patella tendinopathy.

There are still no publications of the combination of eccentric exercise and ESWT. There are some results from other studies but it never was published. One study was from Peers et al. But they had only a follow up period of twelve weeks. This study showed a significant improvement of VISA-P score. Recently this combination was already tried in treatment of midportion tendinopathy of the Achilles tendon. Rompe et al (2009) compared eccentric exercise with eccentric exercise and ESWT. After four months the recovery is significantly better in the combination group than in the only eccentric exercise group.

## **Study objective**

The purpose of the study is to compare the effect of eccentric exercise in combination with electric shockwave therapy with eccentric exercise and sham shockwave therapy. This is measured with the VISA-P score in short term, middle term and long term period.

## **Study design**

The study is a randomised study looking at the effect of treatment of patella tendinopathy with eccentric exercise and shockwave therapy comparing eccentric exercise with sham shockwave therapy.

The diagnosis is given by a sports doctor with a lot of experience in patella tendinopathy.

After inclusion there is determination of the pain pressure threshold, the VAS score and VISA-P. After the explanation of the eccentric exercise they can do the exercises at home. This will start after the first session with shockwave.

Intervention:

Eccentric exercise: squats on a decline board of 25 degrees. First you must bend your knee, then put the other leg next to the first leg to come up again.

During three months two sessions a day of three sets of fifteen repetitions with one minute rest between the sets. They can do the exercises up to a VAS score = 4, above that stop the exercise. When there is no pain during the exercise you can

use some weights. If the exercise is too painful than you can help yourself to lean on the back of a chair.

shockwave: three treatments with 1000 impulses, 4 Hz and energy level of 0,20 mJ/mm<sup>2</sup> (Peers 2003) with a Sonocore focussed shockwave where the most painful point must be treated. Before the treatment there is no use of anaesthetics or analgesics. The shockwavetherapy is in week 1,2 and 3 after inclusion. An experienced physical therapist do the shockwavetherapy.

sham shockwave: three treatments with 1000 impulses of 0,03 mJ/mm<sup>2</sup> with a absorbing pad. Before the treatment there is no use of anaesthetics or analgesics. The shockwavetherapy is in week 1,2 and 3 after inclusion . An experienced physical therapist do the sham shockwavetherapy.

Sportsactivity during treatment is possible but not above the VAS-score=4. If it's above 4 than it is necessary to adjust the load.

### **Intervention**

not applicable

### **Study burden and risks**

The excentric exercise and shockwavetherapy or sham shockwavetherapy can be a little painfull.

## **Contacts**

### **Public**

Medisch Centrum Haaglanden

burgemeester Banninglaan 1  
Leidschendam 2262 BA  
NL

### **Scientific**

Medisch Centrum Haaglanden

burgemeester Banninglaan 1  
Leidschendam 2262 BA  
NL

## Trial sites

### Listed location countries

Netherlands

## Eligibility criteria

### Age

Adults (18-64 years)

Elderly (65 years and older)

### Inclusion criteria

age: >18 years

VISA-P at baseline < 80

min 1 hour sports a week

min 8 weeks pain of the patella tendon

pain with palpation at the insertion of the patellatendon

one side or two sides pain

### Exclusion criteria

local steroid injection in the last month

last 6 months no immunesuppressiva or coricosteroids

damaged or reconstructed anterior cruciate ligament

treatment of patellatendon with excentric exercise or shockwave before

inflammatory diseases of the joints

pregnancy

surgery of the patellatendon

local infections around the patellatendon

other knee pathology

anticoagulantia

pathology of coagulation

## Study design

## Design

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):	01-09-2011
Enrollment:	80
Type:	Actual

## Ethics review

Approved WMO	
Date:	17-06-2011
Application type:	First submission
Review commission:	METC Leiden-Den Haag-Delft (Leiden)
	metc-ldd@lumc.nl

Approved WMO	
Date:	29-09-2011
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden)
	metc-ldd@lumc.nl

Approved WMO	
Date:	11-09-2013
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden)
	metc-ldd@lumc.nl

## 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	NL36153.098.11