

# Effectiveness of Extracorporeal Shockwave Therapy in Jumping Athletes with Patellar Tendinopathy

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Aim of this study is to determine the effectiveness of ESWT on pain, symptoms and function, in athletes with patellar tendinopathy (in an early stage of the disease) who are still able to train and compete.

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

## Summary

### ID

NL-OMON31435

### Source

ToetsingOnline

### Brief title

TOPGAME-study

### Condition

- Tendon, ligament and cartilage disorders

### Synonym

jumper's knee, patellar tendinopathy

### Research involving

Human

### Sponsors and support

**Primary sponsor:** Universitair Medisch Centrum Groningen

**Source(s) of monetary or material Support:** ZonMw;programma Sport;Bewegen en Gezondheid

## Intervention

**Keyword:** jumper's knee, patellar tendinopathy, shockwave therapy

## Outcome measures

### Primary outcome

Change in VISA score.

The VISA score is a simple, reliable instrument for measuring the severity of patellar tendinopathy and is sensitive to small changes in symptoms. It was specifically designed for patellar tendinopathy, rating pain, symptoms, simple test of function and the ability to play sports.

### Secondary outcome

- Answer to the question: \*How is your knee now as compared with before treatment?\*
- Rate the pain on a Visual Analogue Scale (VAS) in which 0 represents no pain, and 100 maximal pain:
  - during activities of daily living (ADL),
  - during sports,
  - during a functional test: the single leg decline squat (SLDS)
  - during a jumping test
- Rate overall treatment satisfaction
- Answer the question if they would recommend ESWT treatment to family or friends

- Ultrasound characteristics (hypo-echogenity, diameter, calcifications, neovascularisation)

- Side effects and adverse reactions/events

- Concurrent (para)medical consumption

## Study description

### Background summary

Patellar tendinopathy is a common overuse injury that often has a major impact on the knee function and even on the career of jumping athletes. There is no consensus about the most appropriate treatment but Extracorporeal ShockWave Therapy (ESWT) appears to be a promising treatment. Until now its effectiveness has only been studied in patients with chronic recalcitrant patellar tendinopathy.

### Study objective

Aim of this study is to determine the effectiveness of ESWT on pain, symptoms and function, in athletes with patellar tendinopathy (in an early stage of the disease) who are still able to train and compete.

### Study design

Double blinded, randomized controlled study using a 2 group repeated measures design with a treatment period of 2 weeks and a 6 month follow-up

### Intervention

Extracorporeal Shockwave Therapy (ESWT)

One group will receive three ESWT treatments at a weekly interval, the other group will receive three placebo ESWT treatments at a weekly interval

### Study burden and risks

ESWT appears to be an effective treatment so this can be of great benefit to

the subject receiving this treatment. Further to this subjects within the placebo group will be offered ESWT treatment after 6 months in case of proven effectiveness so they can benefit from this study as well. On the other hand, the risks and the burden for the subjects both are low. Only 1 inclusion, 3 short treatment and 3 short minimally demanding evaluation visits to a sports medicine centre are necessary during a sport season. Athletes can continue to participate in their sporting activities during the study. There is only a very, very small chance that (serious) side effects of ESWT will occur. So the potential high benefit and the low risk and burden to the subject justify this relevant study into the effectiveness of ESWT in actively playing athletes.

## 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

Male and female athletes with the following criteria are eligible for inclusion:

- History of knee pain in patellar tendon or its patellar or tibial insertion in connection with training and competition
- Symptoms for over three months in the actual season or in the second half of the previous season (January - May 2008) (to exclude acute inflammatory tendon problems and partial ruptures)
- Age 18-35 years old (to reduce the chance of other osteochondrotic diseases like Sinding-Larsen-Johanson, Osgood-Schlatter and osteoarthritis)
- Palpation tenderness to the corresponding painful area
- VISA score < 80

## Exclusion criteria

Athletes must not be included if one of the following applies:

- acute knee or patellar tendon injuries
- chronic joint diseases
- signs or symptoms of other coexisting knee pathology
- contraindications for ESWT (pregnancy, malignancy, coagulopathy)
- knee surgery or injection therapy with corticosteroids in the last preceding three months
- daily use of drugs with a putative effect on patellar tendinopathy in the last year (e.g. non-steroid anti-inflammatory drugs, fluorochinolones) or actual use of anticoagulants

## 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:	Pending

Start date (anticipated): 01-04-2008  
Enrollment: 86  
Type: Anticipated

## Medical products/devices used

Generic name: Extracorporeal Shockwave Therapy  
Registration: Yes - CE intended use

## Ethics review

Approved WMO  
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	NL19389.042.08