The effect of radial and focused shockwave therapy on tendon structure in patients with patellar tendinopathy and healthy subjects: a pilot study

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The primary objective is to get a first insight what the effect of FSWT and RSWT is on the tendon structure in treating patellar tendinopathy patients and on healthy tendons determined by UTC.The secondary objective is to compare the effect of FSWT...

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

Summary

ID

NL-OMON41000

Source
ToetsingOnline

Brief title
TOPSHOCK UTC-study

Condition

- Tendon, ligament and cartilage disorders

Synonym
jumpers knee, patellar tendinopathy

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: Patellar tendinopathy, Shockwave therapy, Tendon structure

Outcome measures

Primary outcome

The primary study parameter is the echo type percentage of the structure of the patellar tendon determined by the UTC device. The UTC is an imaging technique for tendons. It displays the density and arrangement of the collagenous matrix. The tendon structure can be divided into four different echo types, type I, type II, type III and type IV. Type I and II are considered as organized tendon structure, where type III and IV are considered as degenerative tendon structure.

Secondary outcome

The secondary study parameters are the following:

- Self reported VISA-P score: The VISA-P score is a simple, reliable instrument for measuring the severity of patellar tendinopathy and is sensitive to small changes in symptoms. The VISA-P was specifically designed for patellar tendinopathy, rating pain, symptoms, simple test of function and the ability to play sports. Six of the eight questions are scored on a VAS from 0 to 10 points, with 10 representing optimal health. The maximum VISA-P score for an asymptomatic athlete is 100 points.

- Pain on a Visual Analogue Scale (VAS) in which 0 represents no pain, and 100 maximal pain:

during rest

during activities of daily living (ADL),

during sports

after sports

during a functional test: the single leg decline squat (SLDS); the athlete performs one time a single leg squat to 60° of knee flexion on a 25° decline board. This test was designed to preferentially load the patellar tendon.

during a functional test: the single leg decline squat (SLDS); the athlete performs ten times a single leg squat to 60° of knee flexion on a 25° decline board. This test was designed to preferentially load the patellar tendon.

- Perceived improvement, with use of a 4-grade scale as *no symptoms*, improved, but still symptomatic*, *no change*, *worse*. (for PT subjects only)

- Sport participation, sport level and sport activity throughout the study

- Participant characteristics: Age, gender, length, weight

Study description

Background summary

Patellar tendinopathy (PT) is a commin injury, especially among athletes. Patella tendinopathy is experienced as activity-related pain at the patellar tendon. This injury can be a long lasting injury, can have consequences even in daily life and can end an athletes carreer. Currently there is still no consensus what the most appropriate treatment is for this injury. A relatively new and common used treatment option is shockwave therapy (SWT). Several

studies showed SWT can have a positive effect on the symptoms that come with patellar tendinopathy. There are currently two SWTs possible, focused shockwave therapy (FSWT) and radial shockwave therapy (RSWT). A study has shown that both SWT options seem effective on the symptoms of patellar tendinopathy and that there seem to be no difference in effectiveness. Currently it remains unclear what effect SWT has on the tendon strucuture in patellar tendinopathy and healthy tendons. Until recently it was not possible to quantify the tendon structure. With the development of the ultrasonographic tissue characterization device, this became possible.

Study objective

The primary objective is to get a first insight what the effect of FSWT and RSWT is on the tendon structure in treating patellar tendinopathy patients and on healthy tendons determined by UTC.
The secondary objective is to compare the effect of FSWT and RSWT on the symptoms in treating patellar tendinopathy patients.

Study design

The study will be a randomized controlled study with a 4 group repeated measures design. Groups are devided in FSWT group with PT patients (N=15), FSWT group with healthy subjects (N=15), RSWT group with PT patients (N=15) and RSWT group with healthy subjects (N=15).
Participants will be computer randomized in either the FSWT or RSWT group. PT patients will receive SWT on their symptomatic knee, healthy subjects will all receive SWT on their right knee. A 2 week treatment period (3 SWT treatments with a 1 week interval) and a 12 week follow-up for PT patients only as exercise therapy is continued with PT patients only. UTC scans are done before and after each shockwave treatment (T1-T3) and 1 week (T4), 6 weeks (T5) and 12 weeks (T6) after the final shockwave treatment. Healthy subjects are finished after T4. During each evaluation the VISA-P score, VAS pain scale during rest, ADL and during and after sports and the single leg decline squats are determined on all subjects. Rating of subjective improvement is examined on PT subjects only. Throughout the study the subjects will record their sport activities. All treatments and tests are executed at the UMCG.

Study burden and risks

The amount of visits is group dependent.
Healthy subjects will be asked to visit the UMCG 4 times. During 3 visits they will receive SWT and 2 UTC scans each visit. 1 week after the final SWT treatment, a final UTC scan is made. During this period, subjects will be asked not to participate in high intensity explosive sports and avoid jump related activities/sports.
During each visit the VISA-P, VAS pain scale during rest, ADL and during and

after sports, VAS pain scale after 1 and 10 single leg decline squads will be measured.
Possible side effect from the SWT treatment is the only risk for the healthy subjects. But since the energy level is set low, the chances on side effects are minimal.

Subjects from the PT group will be measured a total of 6 times. All measurements are done when they are already expected at the UMCG. When the subject chooses to follow physiotheraphy externally, one extra visit to the UMCG is necessary. The same protocol as in the healthy subjects is followed. However, PT subjects will receive an exercise program (usual care after SWT) after their last SWT treatment, and are also measured 6 and 12 weeks after their final SWT treatment. During each visit the VISA-P, VAS pain scale during rest, ADL and during and after sports, VAS pain scale after 1 and 10 single leg decline squats will be measured. Rate of perceived improvement, with use of a 4-grade scale as *no symptoms*, improved, but still symptomatic*, *no change*, *worse" is also recorded.
The treatment protocol does not differ in any way from the regular treatment. Therefore, no extra risks are present for the PT group during this study.

UTC scans are pain and risk free without any side effects.

Additional time is approximately 30 minutes per visit.

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 subjects with the following criteria are eligible for inclusion in patellar tendinopathy subject group:
- History of knee pain in patellar tendon or its patellar or tibial insertion in connection with training and competition
- Symptoms for over three months
- Age 18-45 years old
- Palpation tenderness to the corresponding painful area
- Degenerative tendon changes determined by a regular ultrasound echo
- VISA-P score < 80;Male and female subjects with the following criteria are eligible for inclusion in healthy subject group:
- Age 18-45 years old
- VISA-P score of 95 or higher

Exclusion criteria

Subjects must not be included in the patellar tendinopathy subjects group if one of the following applies:
- acute knee or patellar tendon injuries
- chronic knee joint diseases
- signs or symptoms of other coexisting knee pathology
- contraindications for SWT (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, fluorchinolones) or actual use of anticoagulants;Subjects must not be included in the healthy subjects group if one of the following applies:
- acute knee or patellar tendon injuries
- history of patellar tendinopathy
- chronic joint diseases
- contraindications for SWT (pregnancy, malignancy, coagulopathy)
- daily use of drugs with a putative effect on patellar tendinopathy in the last year (e.g. non-steroid anti-inflammatory drugs, fluorchinolones) or actual use of anticoagulants

- Allergy or intolerance for paracetamol

Study design

Design

Study phase:	4
Study type:	Observational non invasive
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):	13-02-2015
Enrollment:	60
Type:	Actual

Ethics review

Approved WMO Date:	15-01-2015
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO Date:	15-12-2016
Application type:	Amendment
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

ID: 29199
Source: Nationaal Trial Register
Title:

In other registers

Register	ID
CCMO	NL50792.042.14
OMON	NL-OMON29199