Effect of shockwave therapy on patellar tendon structure

Gepubliceerd: 10-03-2015 Laatst bijgewerkt: 15-05-2024

N/A

Ethische beoordeling	Positief advies
Status	Werving gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON29199

Bron
NTR

Verkorte titel
TOPSHOCK-UTC study

Aandoening

Patellar tendinopathy, Jumper's knee
Dutch: patella tendinopathie, springersknie

Ondersteuning

Primaire sponsor: University Medical Center Groningen (UMCG)
Overige ondersteuning: University Medical Center Groningen (UMCG)
Fyzzio

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

tendon structure as determined with ultrasonographic tissue characterisation (UTC)(expressed in echo type percentages)

Toelichting onderzoek

Achtergrond van het onderzoek

Relevance:

Despite its frequency and impact on athletic careers and in spite of decades of research, management of patellar tendinopathy remains frustrating and unpredictable for both athletes and clinicians. FSWT and RSWT appears to be a promising treatment method in patients with chronic patellar tendinopathy, referred to a sports medicine department after other conservative treatments had failed.

However, it remains unknown what effect FSWT and RSWT have on the tendon structure. To better understand the effect of FSWT and RSWT, it is important to evaluate the effect on the tendon structure in healthy subjects and patients with patellar tendinopathy.

Objective:

The aim of the study is to evaluate the effect of FSWT and RSWT on the tendon structure in healthy subjects and in patients with patellar tendinopathy.

Study design:

A randomized controlled pilot study using a 4 group repeated measures design. Groups are divided 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). A shockwave treatment period of 2 weeks (3 treatments with a 1 week interval) will be applied and a 12 week follow-up with exercise therapy for PT patients only. Results are analyzed with a multilevel analysis

Main study parameter:

Tendon structure in echotype percentages determined by UTC.

Doel van het onderzoek

N/A

Onderzoeksopzet

1. Before and after first treatment (healthy and PT group)

2. Before and after second treatment (healthy and PT group)

3. Before and after third treatment (healthy and PT group)

4. 1 week after final treatment (healthy and PT group

5. 6 weeks after final treatment (PT group only)

6. 12 weeks after final treatment (PT group only)

Onderzoeksproduct en/of interventie

Patients and subjects receive three sessions of either focused shockwave therapy (FSWT) or radial shockwave therapy (RSWT) with an one week interval. Patellar tendinopathy patient receive shockwave therapy in combination with eccentric decline squat training.

Contactpersonen

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

Male and female subjects with the following criteria are eligible for inclusion in patellar tendinopathy (PT) 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 (to exclude acute inflammatory tendon problems and de novo partial ruptures)

• Age 18-45 years old (to reduce the chance of other osteochondrotic diseases like Sinding-Larsen-Johanson, Osgood-Schlatter and osteoarthrosis)

• 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

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

Subjects must not be included in the PT 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

• Allergy or intolerance for paracetamol

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 knee 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

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Open / niet geblindeerd
Controle:	N.v.t. / onbekend

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	13-02-2015
Aantal proefpersonen:	60
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	10-03-2015
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 41000
Bron: ToetsingOnline
Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL4966
NTR-old	NTR5088
CCMO	NL50792.042.14
OMON	NL-OMON41000

Resultaten

Samenvatting resultaten
N/A