Progressive Tendon-loading exercise therapy for patellar tendinopathy in jumping athletes: A randomized controlled clinical trial evaluated with advanced 3D UTE MRI

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The primary aim of this research program is to assess whether the 4-stage exercise protocol is more effective than the usual painful heavy-load eccentric exercise protocol for the treatment of patellar tendinopathy in jumping athletes.Secondary aims...

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

Summary

ID

NL-OMON53044

Source
ToetsingOnline

Brief title
Exercise therapy for patellar tendinopathy evaluated with advanced UTE-MRI

Condition

- Tendon, ligament and cartilage disorders

Synonym
Jumper's knee

Research involving
Human

Sponsors and support

Primary sponsor: Erasmus MC, Universitair Medisch Centrum Rotterdam
Source(s) of monetary or material Support: GE Healthcare

Intervention

Keyword: MRI, patella tendinopathy, Progressive Tendon-loading exercise therapy

Outcome measures

Primary outcome

The primary outcome measure is the change in Victorian Institute of Sports Assessment - Patella (VISA-P) score. The VISA-P score is a simple, validated and 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 participate in tendon-loading sports .

Secondary outcome

Secondary, we will explore baseline characteristics (personal characteristics, additional questionnaires and results of functional tests) that can aid in predicting the prognosis for these patients.

For the secondary imaging outcome measures, we will measure the change over time of the parameters between both treatment groups (treatment response), correlate the imaging parameters with the clinical symptoms and determine the prognostic value of the baseline imaging parameters on the progression of clinical symptoms. The following measurements will be performed:

MRI:

- Conventional: maximum anterior-posterior (AP) thickness and signal abnormalities (intratendinous, peritendinous).
- 3D UTE Cones: T2* relaxation time

Ultrasonography:

- Grey scale: maximum anterior-posterior (AP) thickness, presence of calcifications.
- PDU: Doppler signal (neovascularisation score determined with the modified Ohberg Scale).
- SWE: semi-quantitative assessment with SWE color maps, mean and maximum tissue rigidity (kPa) and mean and maximum shear wave speed (m/s). These outcome measurements will be compared to the results obtained in healthy athletes in order to investigate the diagnostic presentation of patellar tendinopathy on shear-wave elastography (SWE).

- Accuracy: using 5-point likert scale by 3 experts (1: very inaccurate / misleading; 2: inaccurate; 3:somewhat accurate; 4: accurate; 5: very accurate)
- Comprehensiveness: using 5-point likert scale by 3 experts (1: very incomprehensive; 2: incomprehensive; 3:somewhat incomprehensive; 4: comprehensive; 5: very comprehensive)
- Readability: Flesch-Kincaid Grade Level (FKGL): a validated readability formula: 0.39*(total words/total sentences)*+*11.8*(total syllables/total words)***15.59. lower score represents *easy to read* and higher score represents most difficult to read.
- Understandability and actionably: The Patient Education Materials Assessment

Tool (PAMET). Score from 0% (low) to 100% (high).

- Variability: The model ChatGPT is inherently stochastic, which means that it could generate different or random answers even if identical queries are submitted. Besides the default setting of the chatbot and the utility standalone queries, we still test the variability of ChatGPT*s generating answers by entering five questions from each domain after 1 week, 2 weeks and 1 month after initial submission. We will employ 2 versions of queries at each time to shed light on this potential limitation: the same queries as initial and paraphrased queries. A further detailed analysis will be undertaken.

Study description

Background summary

Patellar tendinopathy is a frequent overuse injury that causes pain and impaired performance in jumping athletes. Exercise therapy is considered the best initial treatment option for tendinopathies as clinical improvements in pain and function have been demonstrated.
Although painful eccentric exercise protocols have been promoted as standard care based on positive results in early studies, a recent systematic review demonstrated that these are not associated with improved tendon structure and are ineffective when applied in-season. Progressive tendon-loading exercise therapy for patellar tendinopathy constitutes a novel concept in sports medicine.

A recent study advocates a progressive 4-stage criteria-based exercise protocol as it results in a less reactive tendon and ability to restore collagen alignment. This protocol consists of progressive isometric, isotonic, plyometric, and sport-specific exercises. Isometric exercises have been shown to reduce pain and decrease motor cortex inhibition of the quadriceps.

This approach would enable jumping athletes to resume sports within the limits of pain, with improved muscle function, and sufficient tendon structure re-organization.

The diagnostic imaging work-up of patellar tendinopathy typically consists of

ultrasound, magnetic resonance imaging (MRI), or a combination of both. Ultrashort echo time (UTE) MRI is an advanced MRI technique, which enables assessment of tissues with short T2-time, such as tendon, the structure of which is invisible on regular MRI. UTE has been shown to quantitatively depict changes in tendon microstructure and therefore allows in-vivo evaluation of tendon regeneration. It is currently unknown whether quantitative UTE MRI parameters change after exercise treatment, are related to clinical symptoms of patellar tendinopathy, have prognostic value for exercise treatment response, and offer additional value over ultrasound.The ultrasound features that are typically altered in patients with patellar tendinopathy are Doppler characteristics (increased blood flow is observed in patients) and shear wave elastography (SWE) properties (tendon softening is associated with symptoms, however the exact diagnostic manifestation of patellar tendinopathy compared to healthy athletes is not well known).

Long term follow-up data of athletes with patellar tendinopathy are currently scarce. There is a need for more knowledge on the course of this injury in the long term.

Recently, large language models (LLMs), such as ChatGPT, use artificial intelligence to engage people with human-like conversation. It is reasonable to assume that ChatGPT could improve care by learning and producing language to assist patients in communication with healthcare workers and with each other. No study has assessed the performance of this LLM to address inquiries related to patellar tendinopathy care

Study objective

The primary aim of this research program is to assess whether the 4-stage exercise protocol is more effective than the usual painful heavy-load eccentric exercise protocol for the treatment of patellar tendinopathy in jumping athletes.

Secondary aims are
1) to explore baseline characteristics (personal characteristics, other questionnaires and results of functional tests) that can aid in predicting the prognosis for these patients,

2) to validate a novel 3D UTE MRI pulse sequence for quantitative imaging of the patellar tendon, by determining its responsiveness to exercise treatment, its correlation with clinical symptoms over time, and its predictive value of treatment response,

3) to develop novel quantitative 3D UTE MR imaging biomarkers for the assessment of patellar tendinopathy with the use of advanced image analysis and machine learning methods and

4) to establish the value of ultrasound parameters (neovascularisation score and tendon stiffness as measured with SWE) in responsiveness to treatment, correlation with symptoms, and prediction of symptoms.

The third aim, we will also assess persistence of symptoms, participation in sports, change in functional test results and ultrasonographic appearance of the patellar tendon at long term (5 years) follow-up.

Forth aim: We will evaluate the performance of ChatGPT (Chat Generative Pretrained Transfomer) in answering patient-centered queries related to patellar tendinopathy care.

Study design

Single-blind randomized controlled trial

Intervention

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Study burden and risks

The burden of participation consists of completing a total of 3 hospital visits for inclusion at baseline and follow-up at 12 and 24 weeks.
At inclusion, the patients will be examined by a sports physician and resident radiology resident (ultrasound, under supervised by a MSK radiologist) for eligibility, complete questionnaires, perform functional tests, receive instructions about the exercise therapy and receive the baseline MRI scan.

At the 12 and 24 week follow-up appointments, the patients will complete the questionnaires, the principal investigator will perform physical examination and functional tests and the patients will receive the follow-up MRI scan and ultrasound examination. At 6 and 18 weeks follow-up, an online questionnaire will be completed. The burden of the healthy volunteers consists of a single visit to the ultrasound department of the hospital to undergo an ultrasound of both knees by two trained researchers. There is no follow-up for these healthy volunteers.

No drugs will be administered in the context of this study, and no adverse events are to be expected resulting from both exercise regimens under evaluation. MRI and ultrasound will be performed without contrast agents.

All patients will be screened for contra-indications for MRI, such as metallic implants, pregnancy, etc.

Both groups are expected to benefit from the exercise therapy as we expect

symptom reduction in both groups.

All potential participants will be examined by an experienced sports physician and the diagnosis will be confirmed using additional imaging, so we will provide them with an adequate diagnosis without additional healthcare costs.

Patients will receive one more questionnaire at 5 years follow-up to explore the long-term outcome of this chronic sports-related injury among athletes. Completing this questionnaire is estimated to take 15-20 minutes. Additionally, if these patients are willing to attend the hospital, we will re-test their physical function and apply ultrasound to monitor their knee structure. This will take approximately 45 minutes.

10 patients will receive a questionaire to fill out concerning

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

- Age 18-35 years old
- History of knee pain in patellar tendon or its patellar or tibial insertion in association with training and competition
- Playing sports for at least 3 times a week
- Palpation tenderness to the corresponding painful area
- On ultrasound, there needs to be a fusiform tendon thickening and/or decreased tendons structure and/or increased Doppler signal within the patellar tendon
- VISA-P score < 80/100 points

Only age and sport frequency are applicable for the healthy volunteers recruited. We will also perform a tendon loading test (single leg squat) and tendon palpation and the volunteers will complete the VISA-P questionnaire to ensure that they are asymptomatic.

Exclusion criteria

- Known presence of inflammatory joint diseases (e.g. spondylarthropathy, gout or rheumatoid arthritis) or familial hypercholesterolaemia.
- Contraindications for MRI (pregnancy, metallic implants, etc.)
- Daily use of drugs with a putative effect on the patellar tendon in the preceding year (e.g. fluoroqinolones and statins)
- Knee surgery in the history of the index knee
- Previous patellar tendon rupture of the index knee
- Local injection therapy with corticosteroids in the preceding 12 months
- Daily exercise therapy with a minimum duration of 4 weeks in total in the preceding 12 months
- Acute knee or patellar tendon injuries
- Inability to perform an exercise program
- Participation in other concomitant treatment programs
- Signs or symptoms of other coexisting knee pathology on physical examination (such as joint effusion and joint line tenderness) or additional diagnostics (Chondral lesion of the patella or trochlea on MRI or prepatellar bursitis on US

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)
Control:	Active
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	09-01-2017
Enrollment:	101
Type:	Actual

Ethics review

Approved WMO Date:	10-10-2016
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	22-11-2017
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	28-02-2022
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	14-03-2024
Application type:	Amendment

Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

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	NL58512.078.16