Effect of the use of a patellar strap and sports tape on jumper*s knee complaints

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Primary Objective: Determining the effect of a patellar strap and sports tape on pain and sport participation in subjects with patellar tendinopathy. Secondary Objective(s): Determining the relationship between injury specific, sports related and...

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

Summary

ID

NL-OMON39696

Source
ToetsingOnline

Brief title
TOPPRO-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: ZonMW

Intervention

Keyword: complaints, patellar strap, patellar tendinopathy, sports tape

Outcome measures

Primary outcome

The Visual Analogue Scale (VAS) for pain will be used as the main study outcome in both parts of the study. With this measure subjects indicate on a continuous line between two end points their level of pain. The VAS pain scale is a valid and reliable measure of chronic and acute pain intensity (Bijur, Silver, & Gallagher, 2001) (Downie et al., 1978).

In the first part, the primary study parameter is the VAS pain score after ten single leg decline squats. In the second part of the study, the primary study parameter is the difference between the baseline and the intervention week in the average score on the VAS pain scale during sports.

Secondary outcome

In the first part of the study, the secondary study parameter is the VAS pain score after the maximal vertical jump test and the triple hop test. Furthermore, the height in meters of the highest jump during the maximal vertical jump test for each condition and the distance in meters that is covered by three jumps during the triple hop test are considered secondary study outcomes.

In the second part of the study, the difference in average VAS pain score between the baseline week and the intervention week in the two hours after

sports and the next morning are secondary study parameters. The difference in sports participation (the number and duration of training/matches and missed training/matches a week) between the baseline week and the intervention week is also a secondary study outcome.

Study description

Background summary

Patellar tendinopathy (jumper*s knee) is a clinical condition of gradually progressive activity related pain at the insertion of the patellar tendon at the apex patellae (Blazina, Kerlan, Jobe, Carter, & Carlson, 1973). Prolonged repetitive stress of the knee-extensor apparatus can lead to this common overuse tendinopathy in athletes from different sports. The overall prevalence of patellar tendinopathy among elite and non-elite athletes is high and varies between 3 and 45% (Lian, Engebretsen, & Bahr, 2005) (Zwerver & Bredeweg, 2006). In sports characterized by high demands on speed and power for the leg extensors, such as volleyball and basketball, a prevalence has been reported of 45% and 32% respectively (Lian et al., 2005). Patellar tendinopathy is one of the leading causes for athletes to consult physicians or physical therapists at sports medicine departments. Patellar tendinopathy commonly contributes to the decision to quit an athletic career and also causes mild but long lasting symptoms after the end of an athletic career (Kettunen, Kvist, Alanen, & Kujala, 2002). The high prevalence, low function scores, and chronic nature of the condition result in the fact that patellar tendinopathy can cause at least as much impairment in athletic performance as acute knee injuries (Lian et al., 2005).

A patellar strap or sports tape is used by numerous athletes to reduce pain and to remain active in sports. There are several theories of how such orthoses might work: a patellar strap or tape could increase the patella-patellar tendon angle and hereby reduce the effective length of the patellar tendon (Lavagnino, Arnoczky, Dodds, & Elvin, 2011). This might reduce the load on the tendon. Others think it improves the proprioception (Callaghan, Selfe, Bagley, & Oldham, 2002) or desentisation (Boetje et al, submitted), and therefore decreases the amount of pain that is perceived.

However, there is currently no scientific evidence for the effectiveness of the patellar strap and sports tape in a jumper*s knee. A small pilot study investigated recently the effect of the patellar strap on pain in patellar tendinopathy subjects and showed that the strap possibly has a positive effect

on pain (Boetje et al, submitted). However, this study only measured the acute effect on pain in a small group of athletes and no placebo group was included. Furthermore, the effect of sports tape in jumper*s knee is never studied. Larger and more extended research is necessary to determine the actual effect of both orthoses. In addition, it is interesting to study the effect of the strap or tape in the different severity stages of the injury (Cook & Purdam, 2009). It might be that the orthoses are helpful in the first phase of the injury, but are not effective anymore in a more chronic phase.

Study objective

Primary Objective: Determining the effect of a patellar strap and sports tape on pain and sport participation in subjects with patellar tendinopathy.

Secondary Objective(s): Determining the relationship between injury specific, sports related and personal factors and the effectiveness of patellar strap and sports tape.

Study design

This study is divided into two parts.

The first part is a randomized controlled crossover experiment in a controlled situation in which the effect of the patellar strap and sports tape is examined during several functional tests.

The second part of this study is a randomized controlled trial (parallel group design). After one baseline week subjects will be divided into four different groups.

Intervention

In the first part of the study, all subjects perform three functional tests under four different conditions. The order of the conditions is balanced between subjects. The four conditions are:
- A patellar strap. The strap will be adjusted to the knee according to manufacturer* instructions.
- Sports tape. The tape will be administered by the researcher at the specific site between the patella and the bumb at the start of the tibia (tuberositas tibia).
- Placebo tape. Kinesiotape will be administered by the researcher also at the specific site between the patella and the bumb at the start of the tibia (tuberositas tibia). Because of the characteristics of the kinesiotape (very elastic), this tape gives no support to the patella tendon in contrary to the sports tape.
- Control condition. No intervention is used in this condition.

The three functional tests are shown and explained to the subject. The execution of the tests is preceded by a warming up period of five minutes. The three functional tests are: ten single leg decline squats, the maximal vertical jump test and the triple hop test.

Directly after each test, the participant scores on a VAS pain scale the experienced pain during the test. In addition, the height of the jumps of the maximal vertical jump test and the covered distances of the triple hop test will be documented for each subject.

In the second part of this study subjects are randomly divided into four groups of 35 subjects after stratification for phase. The first week all participants document in a log (in the normal situation) the experienced pain during and after training and matches and the amount of pain the next morning. Further, they document the number and duration of (missed) training and matches. After this week, subjects do the same, but now with one of the following interventions:

1) A patellar strap. Subjects will receive a patellar strap and will be asked to use it for one week during training and matches.
2) Sports tape. Subject will receive sports tape and instructions how to use it. The subject is asked to use it for one week during training and matches.
3) Placebo tape. Subjects receive kinesiotape and instructions how to use it. These instructions are theoretically not effective.
4) Control. The control group will not receive an intervention.

Study burden and risks

The burden associated with participation in this study is small. Subjects only need to visit the sport medical centre once for the first part of the study. In this session, at first the subjects' characteristics (age, length, weight), injury specific characteristics (duration of complaints and phase) and sport related factors (sports, hours performance of sports and duration of participation in sports), are obtained through a baseline questionnaire. Also the VISA-P questionnaire is administered on forehand. After a warming up period of 5 minutes, the tests are executed. After each test the subject indicates on the VAS pain scale the amount of pain that was experienced. In total, this session takes about one hour and 15 minutes.

For the second part of the study, subjects document in a log to what extend they could participate in sports and how much pain they had during and after sports. In addition, at the end of each week they answer a few general questions about the week. The documentation in the log takes every time maximally 5 minutes.

It is necessary to do this study with patellar tendinopathy subjects, because it is impossible to study the effectiveness of the patellar strap and sports

tape on this injury in healthy subjects.

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 18-50 years
-Current symptoms of knee pain in the patellar tendon or its patellar or tibial insertion in connection with training and competition in one or both knees.
-Duration of symptoms for over three months (to exclude acute inflammatory tendon problems and de novo partial ruptures).
-VISA- P score < 80
-Palpation sensitivity in the patellar knee area
-Participating athlete

Exclusion criteria

-Acute knee and patellar tendon problems
-Chronic joint disease(s)
-Signs or symptoms of other knee pathologies

Study design

Design

Study type:	Interventional
Intervention model:	Crossover
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Placebo
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	04-02-2013
Enrollment:	140
Type:	Actual

Ethics review

Approved WMO Date:	25-01-2013
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO Date:	05-02-2014
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: 22717
Source: NTR
Title:

In other registers

Register	ID
CCMO	NL42287.042.12
Other	NTR TC=3660
OMON	NL-OMON22717