# The use of a patellar strap in athletes with a jumper*s knee: A pilot study on the effect on proprioception, tendon structure and symptoms

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Primary Objective: Getting insight in the effect of the use of the Genupoint patellar strap on knee joint proprioception in subjects with patellar tendinopathy.Secondary Objective(s): Getting insight in the effect of the use of the Genupoint...

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

## Summary

### ID

NL-OMON42105

**Source**
ToetsingOnline

**Brief title**
TOPPRO 2 - 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:** Bauerfeind

## Intervention

**Keyword:** Jumper's knee, Patellar strap, Patellar tendinopathy, Symptoms

## Outcome measures

### Primary outcome

The difference in proprioception determined with Mr Cube (Joint Position Sense expressed by the deviation in millimeters from a marker) between both conditions is the primary outcome measure.

### Secondary outcome

The difference in percentage of echotypes 1,2,3 and 4 between the follow up UTC measurement (effect of a patellar strap) compared to the baseline UTC measurement (no patellar strap) are secondary outcomes.

The difference in Visual Analogue Scale (VAS) for pain after ten single leg decline squats between the patellar strap and control condition is also a secondary outcome in this study. The difference in VAS pain score between both conditions (control and strap) during the jump test and the triple hop test are also secondary outcomes, as well as the height (m) and distance (m) measured during these tests.

With the VAS for pain 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 et al., 2001) (Downie et al., 1978).

The VAS pain scores of the different pressures exerted by the strap are also

secondary outcome measures. Finally, the comfort grade (0-10) of wearing the

Genupoint patellar strap is a secondary outcome parameter.

# Study description

### Background summary

Patellar tendinopathy is a common overuse injury that has a major impact on the knee function and often interferes with the sport career of jumping athletes. Orthoses like a patellar strap are often used to reduce the pain in this condition and to be able to remain active in sports. A recent study (TOPPRO METC 2012/378) showed that pain can decrease with the use of a patellar strap, but it is unknown what the effect on proprioception and tendon structure is and if this positive effect can be found with another type of strap. Furhtermore, the relationship between the effectiveness of the use of a patellar strap and tendon structure is unclear. Finally, the force applied by the orthosis might influence the effectiveness.

### Study objective

Primary Objective:

Getting insight in the effect of the use of the Genupoint patellar strap on knee joint proprioception in subjects with patellar tendinopathy.

Secondary Objective(s):

Getting insight in the effect of the use of the Genupoint patellar strap on tendon structure in subjects with patellar tendinopathy.

Studying the effect of the use of the Genupoint patellar strap on pain in subjects with patellar tendinopathy.

Getting first insight in the relationship between the effectiveness of the use of the Genupoint patellar strap and the tendon structure (measured with UTC).

Getting insight in the effect of different amounts of pressure exerted on the tendon on pain relief.
Investigating the comfort of wearing the Genupoint patellar strap.

### Study design

This study is a randomized controlled crossover experiment in which the effect of the Genupoint patellar strap on propriocetion, tendon structure and pain will be examined.

## Intervention

All subjects perform three functional tests (10 single leg decline squats, maximal vertical jump test and a triple hop test) and the Mr Cube proprioception test in two different conditions. The two conditions are: with patellar strap and a control condition. The order of the conditions is balanced between subjects. Directly after each test, the participant scores on a VAS pain scale the experienced pain during the test. Furthermore, the maximal vertical jump height and the distance covered in the triple hop test are documented.

After this, participants wear the Genupoint patellar strap during sports for one week.

The effect on tendon structure and pain is determined by analyzing the UTC scan during the first visit (after one week without strap) and the second visit (after one week with strap) as well as by comparing the sports participation questionnaire at baseline with the questionnaire filled out during the second visit.

During the second visit subjects perform a functional test (10 single leg decline squats) in five different conditions. The five conditions are: -
Control condition: No intervention is used in this condition.
- Normal pressure condition: The pressure of the patellar strap is the preference of the subject.
- Low pressure condition
- Medium pressure condition
- High pressure condition

The five conditions will be randomized. Directly after each test, the participant scores on a VAS pain scale the experienced pain during the test. Also the pressure preferred by the subject is documented.

## Study burden and risks

The burden for the participants in this study is small. Participants are asked to visit the Center for Sports Medicine two times. Both visits take in total two hours.

During the first visit the participants have to fill in two short questionnaires (a baseline questionnaire for the baseline characteristics and a sports participation questionnaire about the previous week). Furthermore the

patellar tendons of the participants are scanned using UTC and the participants are asked to perform ten times the single leg decline squat and score the amount of pain. After this, participants perform a warming up of 5 minutes and execute two times (control and strap) three functional tests. After each test they score the experienced amount of pain. After this the Mr Cube test will be executed two times (control and strap).

Participants use for one week the Genupoint patellar strap during sports and after this they visit again the Center for Sports Medicine. During this visit they answer some questions about the sports participation that week with the strap and the comfort of the strap. Further, the patellar tendons are scanned using UTC. After this participants perform five times the 10x single leg decline squat where the pressure exerted by the patellar strap is manipulated.

The research question can only be answered when participants with patellar tendinopathy are included and the effect of the strap is investigated in this group of subjects.

## Contacts

**Public**
Universitair Medisch Centrum Groningen

Hanzeplein 1
Groningen 9713 GZ
NL
**Scientific**
Universitair Medisch Centrum Groningen

Hanzeplein 1
Groningen 9713 GZ
NL

## 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).
- Palpation tenderness at the corresponding painful area.
- VISA-P score < 80.
- Participating athlete
- No use of a patellar strap during sports in the week prior to the study.
- Written informed consent.

## Exclusion criteria

- Acute knee or acute patellar tendon injuries
- Chronic joint disease(s)
- Signs or symptoms of other (co-)existing knee pathologies
- Use of drugs with a putative effect on patellar tendinopathy in the last year on daily basis or painkillers
- Neurologic disorders which might influence pain and proprioception
- Knee surgery or injection therapy with corticosteroids in the last preceding three months

# Study design

## Design

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| Study type: | Interventional |
| Intervention model: | Crossover |
| Allocation: | Randomized controlled trial |
| Masking: | Open (masking not used) |

**Primary purpose:** Treatment

### Recruitment

NL

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| Recruitment status: | Recruitment stopped |
| Start date (anticipated): | 17-03-2015 |
| Enrollment: | 25 |
| Type: | Actual |

## Ethics review

Approved WMO

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| Date: | 09-03-2015 |
| 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

ID: 28088
Source: Nationaal Trial Register
Title:

### In other registers

| Register | ID |
|---|---|
| CCMO | NL51658.042.14 |
| OMON | NL-OMON28088 |