

The use of a patellar strap in children with Osgood-Schlatter disease: a pilot study of the short term effect on symptoms and sports participation.

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON21775

Source

NTR

Brief title

Patellar strap in OS.

Health condition

Osgood-Schlatter disease.

Sponsors and support

Primary sponsor: University Medical Center Groningen (UMCG).

Source(s) of monetary or material Support: None.

Intervention

Outcome measures

Primary outcome

The visual analogue scale (VAS) for pain will be used as the main study parameter in both

parts of the study. The visual analogue scale consists of a pre-measured horizontal line, where the ends of the line represent the extreme limits of pain intensity. The child is asked to make a mark along the line to indicate the intensity of his/her pain. Current evidence suggests that visual analogue scales are superior for measuring pain intensity in clinical trials. Visual analogue scales have been extensively researched and show good acceptability, responsiveness and validity for children aged 8 years and older. An advantage of the visual analogue scales is the increased responsiveness in pain intensity scoring due to the interval or ratio measurement continuum. We have chosen to use the Faces Pain Scale-Revised in addition to the visual analogue scale. This is especially advised for children between the ages of 8 and 12 years, as it might reduce failure rates.

First part of the study:

VAS pain score after ten single leg decline squats (for each condition).

Second part of the study:

The difference in the average VAS pain score during sports between the baseline week and the intervention week.

Secondary outcome

First part of the study:

- VAS pain score after the maximal vertical jump test.
- VAS pain score after the triple hop test.
- The height in meters of the highest jump during the maximal vertical jump test.
- The distance in meters that is covered by three jumps during the triple hop test.

Second part of the study:

- The difference in the average VAS pain score the two hours after sports between the baseline week and the intervention week.
- The difference in the average VAS pain score the morning after sports between the baseline week and the intervention week.

Study description

Background summary

Osgood-Schlatter disease is a traction apophysitis of the proximal tibia due to repetitive strain on the secondary ossification center of the tibial tuberosity. This overuse injury is prevalent in growing children, especially boys, who are actively engaged in sports. Osgood-Schlatter disease can negatively influence the course of a child's sports career. Orthosis like a patellar strap are sometimes used to reduce the pain in this condition, so children can continue to be active in sports. However, very little scientific evidence for a positive effect on symptoms and sports participation is available yet.

The main purpose of this study is to evaluate the short term effect of a patellar strap on symptoms and sports participation in children with Osgood-Schlatter disease. The second objective of this study is to determine the relationship between the effectiveness of a patellar strap and injury-specific, sports-specific and personal factors.

Study objective

We expect to find a positive effect on Osgood-Schlatter disease complaints as a result of the use of a patellar strap.

Study design

1. Baseline week (no intervention).
2. Intervention week (patellar strap).

Intervention

This study is divided in two parts. Subjects who participate in the first part of the study are asked to participate in the second part also.

The first part (controlled situation) is a randomized controlled crossover experiment. The subjects serve as their own control by performing three functional tests in three different conditions (in a randomized order). The three conditions are: 1. Patellar strap 2. Placebo tape (kinesiotape) 3. Control condition (no patellar strap/no placebo tape) The three functional tests are: 1. Single leg decline squats 2. Maximal vertical jump test 3. Triple hop test. All subjects will execute all tests under all conditions during one session. The subject directly scores the experienced pain on the VAS pain scale after each 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.

The second part (sport specific situation) is a cohort study. All subjects will have a baseline week (no intervention) and an intervention week (patellar strap), in which they train and compete in their own environment. They will be asked to document the following in a 2-week log: the amount of pain during and after every training/competition and the duration and number of training/competitions.

Contacts

Public

University Medical Center Groningen

P.O. BOX 30001
I. Akker-Scheek, van den
Groningen 9700 RB
The Netherlands
+31 (0)50 3610549

Scientific

University Medical Center Groningen

P.O. BOX 30001
I. Akker-Scheek, van den
Groningen 9700 RB
The Netherlands
+31 (0)50 3610549

Eligibility criteria

Inclusion criteria

1. Age 8-15 years.
2. Diagnosis of Osgood-Schlatter disease based on clinical symptoms in combination with redness, prominence and pain at palpation of the tibial tuberosity.
3. Duration of symptoms for over 4 weeks. 4. SOS score < 80.

Exclusion criteria

1. Signs or symptoms of other knee pathologies.
2. Other injury to the affected leg.

3. Chronic joint disease(s).

Study design

Design

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

Recruitment

NL	
Recruitment status:	Recruiting
Start date (anticipated):	01-10-2015
Enrollment:	40
Type:	Anticipated

Ethics review

Positive opinion	
Date:	24-09-2015
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 42555
Bron: ToetsingOnline
Titel:

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
NTR-new	NL5242
NTR-old	NTR5499
CCMO	NL54011.042.15
OMON	NL-OMON42555

Study results

Summary results

N/A