

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.

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Primary objective: The 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. Secondary objective: The second objective of this study is to...

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

Summary

ID

NL-OMON42555

Source

ToetsingOnline

Brief title

Patellar strap in OS

Condition

- Tendon, ligament and cartilage disorders

Synonym

apophysitis of tibial tuberosity, Osgood-Schlatter disease

Research involving

Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Groningen

Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Complaints, Osgood-Schlatter disease, Patellar strap

Outcome measures

Primary outcome

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.

Study objective

Primary objective:

The 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.

Secondary objective:

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 design

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 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.

Intervention

In first part, participants perform three functional tests (single leg decline squat, maximal vertical jump test, triple hop test) in three different conditions (patellar strap, placebo tape, control condition).

In the second part, participants train and compete in their own environment and fill out a log during a baseline week (no intervention) and an intervention week (patellar strap).

Study burden and risks

The research question can only be answered by studying children with Osgood-Schlatter disease. The outcome of the study outweighs the burden for the children. The estimated duration of the first part of the study is 90 minutes; of the second part 30 minutes. The risks are negligible, as all tests are also performed during physical examination when children visit the outpatient clinic and during usual rehabilitation sessions or sports activities. Knowledge gained with this study can help physicians and physiotherapists to advise children with Osgood-Schlatter disease and their parents regarding the use of a patellar strap.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age

Adolescents (12-15 years)

Adolescents (16-17 years)

Children (2-11 years)

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
Primary purpose:	Treatment

Recruitment

NL	
Recruitment status:	Recruitment stopped
Start date (anticipated):	06-11-2015
Enrollment:	40
Type:	Actual

Ethics review

Approved WMO	
Date:	01-09-2015
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: 21775
Source: NTR
Title:

In other registers

Register	ID
CCMO	NL54011.042.15
OMON	NL-OMON21775