Treatment of Sever's Disease: A Therapeutic Randomized Clinical Trial Wait and See versus Orthotic device versus Physical Therapy

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The goal of this trial is to find the best available conservative treatment, based on subjective pain scores, for children with Sever*s disease. Our primary objective is to score the possible decrease of pain experienced by the subjects. This will...

Ethical review	Approved WMO
Status	Pending
Health condition type	Bone disorders (excl congenital and fractures)
Study type	Interventional

Summary

ID

NL-OMON34516

Source
ToetsingOnline

Brief title
Conservative treatment of Sever's Disease

Condition

- Bone disorders (excl congenital and fractures)

Synonym
Calcaneal apophysitis, heelpain

Research involving
Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum

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

Intervention

Keyword: Apophysitis, Conservative, RCT, Sever's

Outcome measures

Primary outcome

Main study parameters

*The VAS for pressure pain at the insertion of the Achilles tendon into the calcaneus

*Oxford Ankle and Foot Score

Secondary outcome

*Satisfaction with received treatment, scored on a 11-point scale (0 = very dissatisfied to 10 = very satisfied).

*General recovery, experienced by the patient will be measured through a 6 point scale (*complete recovery*, *much improved*, *little improvement*, *unchanged*, *somewhat worse*, *much worse*. Based on the outcome recovery percentages will be calculated, answer options *complete recovery* or *much improved* will be noted as recovery.

Study description

Background summary

Sever*s disease (calcaneal apophysitis) is a traction epiphysitis of calcaneus. Sever*s disease is a common injury. Symptoms present around the age of 7-15 years in boys and 8-13 year in girls. The incidence of Sever*s disease in musculoskeletal injuries has been reported to be between 2 and 16% and is the most common cause of heel pain in the growing child. It is known to have a severe impact on the quality of life of the patients.

Most of the data on effectiveness of treatments are retrospective and based on clinical notes and describe mainly the incidence, symptoms and sex ratio for Sever*s disease. As there is currently no scientific evidence for the treatment of Sever*s disease, the treatment has been described as *a guessing game*. The current treatment, based on marginal scientific evidence is focused on conservative treatment: rest, sport cessation and extensor strengthening; heel lifts; orthoses; stretching and padding of the heel. Most studies report a large decline of pain symptoms after a treatment period of 4-17 weeks. In our centre the most often provided treatment is either the prescription of rest and sports cessation with aditional strengthening of the extensor lower leg muscles, heel lift inlays, or stretching exercises for the lower leg muscles.

Study objective

The goal of this trial is to find the best available conservative treatment, based on subjective pain scores, for children with Sever*s disease. Our primary objective is to score the possible decrease of pain experienced by the subjects. This will be measured using two questionnaires:
*VAS Pain score for pressure pain at the insertion of the Achilles tendon
*Oxford Ankle and Foot Score

Study design

A therapeutic randomized controlled trial, with an intervention period of 10 weeks will be finished after a follow-up period of 12 months. Three different treatment methods will be evaluated during the trial: prescribed stretching exercises, rest and sports cessation for 10 weeks; a continuously worn customized heel raise inlay; supervised strengthening (10 sessions during 10 weeks).

Intervention

Subjects allocated to the heel raise group will need to wear a customized heel raise inlay throughout the whole study period (10 weeks)

Study burden and risks

The treatment is the current treatment (same as the non-research setting), we expected subjects to have a decrease of pain complains, regardless of which treatment they will receive.
Subjects in group 2 (heel raise) may need to grow accustomed to their heel raised shoe. This may be experienced as a burden for subjects. To subjects allocated to group 3 (strengthening program), the first exercise sessions may result in muscle-ache. This should subside as the program continues.

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

* Age between 8 years old and skeletally unmatured children
* Positive squeeze test (Pressure pain at posterior side of heel, located at the insertion of the Achilles tendon).
* Pain complaints for at least 2 weeks prior to the start of treatment
* Able to fill out questionnaires and capable of performing prescribed exercises

Exclusion criteria

* Age under 8 years old or skeletal maturity
* Deviated foot alignment

* Subjects complains based on other pathology
* Subjects or parents/guardians of subjects who are unable to fill out questionnaires and cannot have them filled out

Study design

Design

Study type: Interventional

Masking:	Single blinded (masking used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-09-2010
Enrollment:	108
Type:	Anticipated

Medical products/devices used

Generic name:	shoe supplement
Registration:	Yes - CE intended use

Ethics review

Approved WMO

Application type:	First submission
Review commission:	METC Amsterdam UMC

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: 21027
Source: Nationaal Trial Register
Title:

In other registers

Register	ID
CCMO	NL32540.018.10
OMON	NL-OMON21027