Hielpijn Studie

No registrations found.

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

Summary

ID

NL-OMON21027

Source
NTR

Health condition

Children, male or female, aged between 8 years old and skeletal maturity, will be recruited at the outpatient clinic of the AMC and the practices of general practitioners (GP’s) in the greater Amsterdam area. Children who consulted the AMC or their GP’s for posterior heel pain and pain when palpating the calcaneal apophysis, suspect for Sever’s disease, will be considered to participate.
Subjects are eligible to participate provided they meet the following criteria:

Sponsors and support

Primary sponsor: none
Source(s) of monetary or material Support: none

Intervention

Outcome measures

Primary outcome

• VAS Pain score for pressure pain at the insertion of the Achilles tendon, as measured with an algometer

Secondary outcome

• Oxford Ankle and Foot Score

• Satisfaction with received treatment

• General recovery, experienced by the patient, will be measured through a 6 point scale

• Time to return to pre-injury sports level

Study description

Background summary

Rationale: Sever's disease, or calcaneal apophysitis, is one of the most common causes of heel pain in children aged 9-14. There is currently no evidence and no general consensus on the optimal treatment of this disease. This trial aims to provide necessary evidence for the optimal treatment of Sever's disease.
Objective: to compare 3 conservative treatment strategies to give direction to the discussion on the optimal treatment of Sever's disease. This trial compares three frequently prescribed treatment methods: wait and see policy (stretching and activity cessation) (1), heel raise inlay (2) and a physical therapy strengthening programme (3). The comparison will be based primarily on patient oriented outcome measures.
Study design: Therapeutic randomized clinical trial
Study population: Children, with calcaneal apophysitis (Sever's disease), aged between 8 years old and skeletal maturity.
Intervention (if applicable): One group will receive advice on activity cessation and a stretching program (Group 1), the second will receive a heel raise inlay (Group 2); the third receives a eccentric physiotherapy program (Group 3). The treatment period for each group is 10 weeks
Main study parameters/endpoints: The VAS score for pain at the insertion of the Achilles tendon is the main outcome, it will be evaluated at each consult.

Study objective

The VAS score is lower in subjects with Sever's disease after treatment with heel raise than in subjects treated with supervised strengthening exercises.
The VAS score is lower in subjects with Sever's disease after treatment with supervised strengthening exercises than in subjects treated with prescribed stretching exercises and activity modification.

Study design

Measuring moments are at inclusion, (0 weeks), halfway the treatment (6 weeks), end of treatment period (12 weeks)

Intervention

group 1: wait and see (rest) activity modification easy stretching (10wks)

group 2: heel raise inlay, prefabricated, non-customized, edited to foot size (10wks)

group 3: eccentric exercises under physical therapist supervision(10wks)

Contacts

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Eligibility criteria

Inclusion criteria

• Diagnosis of Sever’s disease, as defined by

o Age between 8 years old and skeletally unmatured children

o Positive squeeze test (Pressure pain at posterior side of heel, located at the insertion of the Achilles tendon).
o Pain complaints for at least 2 weeks prior to the start of treatment
• The VAS score of the heel pain should be at least 3 points

• Capable of filling out a questionnaire, if necessary in consultation with parent(s)

• Capable of performing prescribed exercises

• Informed consent signed by the subject’s parents or guardian(s)

Exclusion criteria

• Age under 8 years old or skeletal maturity

• Deviated foot alignment

• Fracture or tumour of the foot or leg,

• Infective, reactive or rheumatoid arthritis
• Subjects complaints based on other pathology

• Participation in concurrent trials

• Subjects or parents/guardians of subjects who are unable to fill out questionnaires and cannot have them filled out

• No informed consent

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)
Control:	Active

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-12-2011
Enrollment:	96
Type:	Anticipated

Ethics review

Positive opinion
Date: 28-10-2013
Application type: First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 34516
Bron: ToetsingOnline
Titel:

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

No registrations found.

In other registers

Register	ID
NTR-new	NL4095
NTR-old	NTR4241
CCMO	NL32540.018.10
ISRCTN	ISRCTN wordt niet meer aangevraagd.
OMON	NL-OMON34516

Study results

Summary results
N/A