Hielpijn Studie

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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…

Ethische beoordeling	Positief advies
Status	Werving gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON21027

Bron
NTR

Aandoening

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:

Ondersteuning

Primaire sponsor: none
Overige ondersteuning: none

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

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.

Onderzoeksopzet

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

Onderzoeksproduct en/of interventie

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)

Contactpersonen

Publiek

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

• 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)

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

• 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

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Enkelblind
Controle:	Geneesmiddel

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	01-12-2011
Aantal proefpersonen:	96
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	28-10-2013
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 34516
Bron: ToetsingOnline
Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

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

Resultaten

Samenvatting resultaten
N/A