A prospective randomised controlled study to evaluate ankle dorsiflexion after cast immobiliation and percutaneous gastrocnemius lengthening, for neurologic healthy children (6-18) with an symptomatic equinus contracture.

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By making this design study we wish to contribute to profound research on percutaneous gastrocnemius lengthening for for children with an equinus contracture and prevent publication bias for this open-labelled randomized trial.

Ethical review	Approved WMO
Status	Will not start
Health condition type	Musculoskeletal and connective tissue disorders congenital
Study type	Interventional

Summary

ID

NL-OMON38124

Source
ToetsingOnline

Brief title
equinus contracture: cast vs percutaneous gastrocnemius lengthening.

Condition

- Musculoskeletal and connective tissue disorders congenital

Synonym
equinus contracture, short achilles tendon

Research involving

Human

Sponsors and support

Primary sponsor: Spaarne Ziekenhuis
Source(s) of monetary or material Support: lokaal fonds voor Orthopedisch onderzoek

Intervention

Keyword: equinus contracture, idiopathic toe walking, percutaneous gastrocnemius lengthening.

Outcome measures

Primary outcome

Primary end-point will be ankle dorsiflexion.

Secondary outcome

Secondary end-point will be satisfaction, walking pattern, pain, complications,

activity level and foot pressure. Functional outcome will be measured by:

AOFAS-score and functional mobility scale (FMS).

Study description

Background summary

We present the design of an open randomized study on conservative versus surgical treatment of children with an equinus contracture. The study is designed to evaluate the difference ankle dorsiflexion after cast immobilisation versus percutaneous gastrocnemius lengthening for Neurology healthy children (6-18) with an equinus contracture where zonservative treatment had been failed.

Study objective

By making this design study we wish to contribute to profound research on percutaneous gastrocnemius lengthening for for children with an equinus contracture and prevent publication bias for this open-labelled randomized trial.

Study design

Prospective randomised controlled study.
Patients will be randomized to percutaneous gastrocnemius lengthening followed by a below knee cast for 6 weeks and intensive physical therapy for 12 weeks or no surgery but a below knee cast for 6 weeks also followed by physical therapy for 12 weeks. Both treatment arms use a 18 weeks protocol. After 18 weeks the patient will have physical therapy low intensive (once per 4 weeks) until one year after the study starts.

Intervention

percutaneous gastrocnemius lengthening

Study burden and risks

To our knowledge there are no potential risks for the included patients. Percutaneous gastrocnemius lengthening has a little chance of general surgical complications like: woundinfection, thrombosis, bleeding or nerve damage. Cast immobilisation has a chance of thrombosis or presur ulcus.

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

Patients (boys and girls) between 6-18 years
independent walking achieved
symptomatic limited ankle dorsi flexion between -10 and 3 degrees (with knee in extension and ankle in neutral position)
patient has been treated non-surgically for at least 6 month (NSAIDs, stretching, orthoses and physical therapy)
Written informed consent both parents/ guardian (children 6-12 years)
written informed consent both parents/ guardian and child (children 12-18 years)

Exclusion criteria

Patients with signs of neurological, orthopaedic or psychiatric disease.
Patients with mental retardation
Patients with previous surgery on the ankle
Patients who were already treated with castimmobilisation because of equinus contracture
Patients (12 years or older) whose parents are unable to understand informed consent
Patients (12 years or older) or parents who are unable to fill out questionnaires
Patients (12 years or older) or parents who are unable to understand treatment

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Will not start
Start date (anticipated):	01-01-2012
Enrollment:	80
Type:	Anticipated

Ethics review

Approved WMO

Date:	16-04-2012
Application type:	First submission
Review commission:	METC Noord-Holland (Alkmaar)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

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

No registrations found.

In other registers

Register	ID
CCMO	NL33762.094.10