

Results of cast treatment and percutaneous achilles tendon lengthening for children with an achilles tendon contracture.

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

Samenvatting

ID

NL-OMON21028

Bron

NTR

Verkorte titel

AP study

Aandoening

idiopathic toe walkers: children who walked on their toes after the age of two and children who has a symptomatic equinus contracture (ankle dorsiflexion between -10 and 3 degree).

Ondersteuning

Primaire sponsor: wetenschapsbureau Linneus Instituut Spaarne ziekenhuis

Overige ondersteuning: -

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Ankle dorsiflexion.

Toelichting onderzoek

Achtergrond van het onderzoek

Background:

We present the design of an open randomized study of conservative versus surgical treatment for children with an equinus contracture. The study is designed to evaluate the difference in dorsiflexion after treatment with cast immobilization versus percutaneous gastrocnemius muscular lengthening for neurologically healthy children (6-18 years) with a symptomatic equinus contracture unresponsive to non-operative care.

Methods/Design:

80 patients with an equinus contracture will be randomized to percutaneous gastrocnemius muscular 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. Primary end-point will be ankle dorsiflexion. Secondary end-point will be functional outcome, satisfaction, walking pattern, pain, complications, activity level and foot pressure. Patients follow-up will be 1 year.

Discussion:

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

Doel van het onderzoek

It is not unusual for children to have an intermittent tiptoe gait when they start to walk. Older children with persistent tiptoe gait in absence of developmental, neurological or neuromuscular conditions, are diagnosed idiopathic toe walkers (ITW's). Most of the time it resolves spontaneously. Sometimes the plantar flexion has a tendency to persist and it's

possible a equinus contracture develops with time, eventually with permanent shortening of the gastrocnemius. Further a relationship has been reported between persistent toe walking and the development of ankle equinus and recognition is increasing that a wide variety of pathologies are associated with longstanding equinus contracture. The management of children with ITW is still controversial. To our knowledge, there aren't prospective studies to compare cast and surgical treatment.

We hypothesized a mean difference of > 5 degrees passive ankle dorsiflexion after treatment with percutaneous gastrocnemius lengthening, compared to ankle dorsiflexion of children after treatment with cast immobilization, after one year follow-up.

Onderzoeksopzet

This study starts at screening on the outpatient clinic (T0) (table 1). Follow-up visits for assessment of primary and secondary endpoints will be scheduled for both treatment groups after two weeks for plaster change (T2). Thereafter follow-up visits will be planned at six weeks (T3), 12 weeks (T4), 6 months (T5), and one (T6) year, after cast immobilization (T1)

Onderzoeksproduct en/of interventie

Patients will be treated by percutaneous gastrocnemius lengthening. After surgery patients will be placed in a below-knee cast with also minimal weightbearing for 2 weeks and 4 weeks full weightbearing plaster, followed by physical therapy for 12 weeks.

Control: Patients will be treated by a below knee cast, set in plantigrade, with six weeks full weightbearing plaster, also followed by physical therapy for 12 weeks.

Contactpersonen

Publiek

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

1. Patients (boys and girls) between 6-18 years;
2. Independent walking achieved;
3. Symptomatic limited dorsalflexion between -10 and 3 grade (with knee in extension and ankle in neutral position and it improves with knee in flexion);
4. Patients has been treated non-surgically for at least 6 month (NSAIDs, stretching, orthoses and physical therapy);
5. Written informed consent both parents/guardian (when patient < 12 year), written informed consent child and both parents/guardian (when child \geq 12 year).

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

1. Patients with signs of neurological, orthopaedic or psychiatric disease and patients with mental retardation;
2. Patients with previous surgery on the ankle;
3. Patients with previous treatment of cast immobilization because of equinus contracture;
4. Patients (12 years or older) whose parents are unable to give informed consent;
5. Patients (12 years or older) or parents who are unable to fill out questionnaires;
6. Patients (12 years or older) or parents who are unable to understand treatment.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blinding:	Open / niet geblindeerd
Controle:	Geneesmiddel

Deelname

Nederland	
Status:	Werving nog niet gestart
(Verwachte) startdatum:	01-09-2012
Aantal proefpersonen:	78
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies	
Datum:	16-08-2012
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL3433

Register

NTR-old

Ander register

ISRCTN

ID

NTR3584

METC : M011-027

ISRCTN wordt niet meer aangevraagd.

Resultaten

Samenvatting resultaten

N/A