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

No registrations found.

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

Summary

ID

NL-OMON21028

Source
NTR

Brief title
AP study

Health condition

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

Sponsors and support

Primary sponsor: wetenschapsbureau Linneus Instituut Spaarne ziekenhuis
Source(s) of monetary or material Support: -

Intervention

Outcome measures

Primary outcome

Ankle dorsiflexion.

Secondary outcome

1. Walking pattern;

2. Satisfaction;

3. Pain;

4. Complications;

5. Activity level by Functional Mobility Scale;

6. AOFAS hindfoot scale: Measures pain functional activity and other complaints;

7. Ground reaction force. Foot pressure measurement (pre- and posttreatment), using the footscan® USB plate by RS International®. It records the pressure in different parts of the foot during gait. From these readings a pattern of gait is deducted with can be analysed both quantitatively and qualitatively.

Study description

Background summary

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.

Study objective

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.

Study design

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)

Intervention

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.

Contacts

Public

Wijnand Nuijenstraat 54
A.F. Bemmel, van
Amsterdam 1061 WB
The Netherlands
+31 (0)6 34484529
Scientific
Wijnand Nuijenstraat 54
A.F. Bemmel, van
Amsterdam 1061 WB
The Netherlands
+31 (0)6 34484529

Eligibility criteria

Inclusion criteria

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 ≥ 12 year).

Exclusion criteria

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.

Study design

Design

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

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-09-2012
Enrollment:	78
Type:	Anticipated

Ethics review

Positive opinion

Date:	16-08-2012
Application type:	First submission

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
NTR-new	NL3433
NTR-old	NTR3584
Other	METC : M011-027
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Study results

Summary results
N/A