Measuring muscle-tendon properties in a clinical setting in clubfoot patients of different ages

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To investigate the difference in muscle-tendon parameters of 2-11 years old unilateral clubfoot patients by means of 3D ultrasound. Subaims investigate the relation between muscle-tendon properties and age/ functional/clinical status of the clubfoot...

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Musculoskeletal and connective tissue disorders congenital
Study type	Observational non invasive

Summary

ID

NL-OMON56293

Source
ToetsingOnline

Brief title
3D ultrasound by clubfoot patients

Condition

- Musculoskeletal and connective tissue disorders congenital

Synonym
clubfoot, congenital equinovarus talipes

Research involving
Human

Sponsors and support

Primary sponsor: Maxima Medisch Centrum
Source(s) of monetary or material Support: Commissie onderzoek en Innovatie MMC / Stichting AA onderzoek en wetenschap

Intervention

Keyword: 3D ultrasound, clubfoot, functional status, muscle- tendonproperties

Outcome measures

Primary outcome

(difference in) calf-muscle volume

Secondary outcome

secondary muscle-tendon properties such as pennation angle, fiber length and

muscle and tendon cross-sectional area

functional status of the clubfoot according to the Clubfoot Assessment Protocol

clinical status (relapse)

age

Study description

Background summary

Congenital equinovarus talipes, also called clubfoot, is a common congenital disorder occurring in 1.09 - 1.52 per 1000 new-borns. Although the name *clubfoot* implies that it is a disorder of the foot, actually the whole lower extremity including its ligaments, bones, muscles, and tendons are affected in clubfoot. Muscle atrophy of the affected leg in unilateral clubfoot patients seems to increase with age. However previous studies are based on MRI images of a heterogenic small sample of clubfoot patients. Furthermore, these studies did not investigate the muscle-tendon development in clubfoot patients during the last phase of Ponseti treatment and immediately after Ponseti treatment. This phase is especially of interest in relation to change in treatment (with and without brace), the development of a relapse and functional status of the rapid growing foot.

Study objective

To investigate the difference in muscle-tendon parameters of 2-11 years old unilateral clubfoot patients by means of 3D ultrasound. Subaims investigate the relation between muscle-tendon properties and age/ functional/clinical status

of the clubfoot patient.
This information will give insights related to timing and content of possible additional treatment.

Study design

Observational study

Study burden and risks

Participating in the study will not result in a direct advantage for the children and/or their parents. It is expected that patients and parents experience no hindrance or risk from this study, except for the half-hour time investment. Measurements will be combined with a regular out-patient visit at the Máxima MC. Additional imaging (X-ray, MRI, ultrasound) and administration of the Clubfoot Assessment Protocol is common practice in the follow up of clubfoot patients. As compensation for their participation in the study, the children will receive a small gift at the end of the measurement (e.g., sticker sheet).

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Children (2-11 years)

Inclusion criteria

- Idiopathic clubfoot patients
- Unilaterally affected
- 2 t/m 11 years old
- Primarily treated with the Ponseti method
- Relapse group: planned for relapse treatment (e.g. but not limited to tibialis anterior transposition / hemi-epiphysiodesis)

Exclusion criteria

- Patients with underlying syndromes
- Bilaterally affected patients
- Patients who had primary treatment for their clubfoot other than the Ponseti method

Study design

Design

Study type: Observational non invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	15-01-2024
Enrollment:	35
Type:	Actual

Medical products/devices used

Registration:	No

Ethics review

Approved WMO Date:	06-11-2023
Application type:	First submission
Review commission:	METC Maxima Medisch Centrum (Veldhoven)
Approved WMO Date:	17-07-2024
Application type:	Amendment
Review commission:	METC Maxima Medisch Centrum (Veldhoven)

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
Other	is in aanvraag (reactie in overleg met Y de Haan)
CCMO	NL84721.015.23