# Gait analysis in healthy children to obtain normative data for gaitanalysis in children with clubfeet

Published: 09-10-2015
Last updated: 19-04-2024

Obtain normative data within similar age-range as our clubfoot patients.

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|---|---|
| **Ethical review** | Approved WMO |
| **Status** | Recruitment stopped |
| **Health condition type** | Other condition |
| **Study type** | Observational non invasive |

## Summary

### ID

NL-OMON47326

**Source**
ToetsingOnline

**Brief title**
Gait analysis in children

### Condition

- Other condition

**Synonym**
controls, healthy children

**Health condition**

gezonde kinderen

**Research involving**
Human

## Sponsors and support

**Primary sponsor:** Catharina-ziekenhuis
**Source(s) of monetary or material Support:** SIA RAAK Publiek,Cooperatie Orthopedie Groot Eindhoven (Catharina ziekenhuis/Maxima Medisch Centrum) / Fontys Paramedische Hogeschool

## Intervention

**Keyword:** Gait analysis, Normative data

## Outcome measures

### Primary outcome

Maximum dorsal and plantaiflexion of the ankle during gait-cycle.

### Secondary outcome

Addition results gaitanalysis: range of motion knee and hip / ankle power /

foot progression angle - intoeing / footpressure.

Stiffness of the foot / diameter of hamstrigs

# Study description

### Background summary

The treatment of children with clubfeet who visit our outpatient clinic is prospectively followed. Gait analysis, a measurement of the stiffness of the feet and ultragraphy of the calf-muscles are part of the cohort. Since the unaffected side in children with unilateral clubfoot is not comparable with a healthy normal feet we would like to test healthy children to obtain normative data.

### Study objective

Obtain normative data within similar age-range as our clubfoot patients.

### Study design

Observational study, including 1 or 2 measument of approximately 60-75 minutes.

If only the stiffness is measured, the duration is estimated at +-15 minutes

**Study burden and risks**

Measurements will be performed by skilled researchers. Participants and parents are asked to come to lab for a measurement of approximately 60-75 minutes. If only the stiffness measure takes place, measurement could take place at hospital. Considering to unfamiliar location and the unknown measurements it might be that participants will be slightly tired after testing. No additional burder and/or risks are expected.

# Contacts

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# Trial sites

## Listed location countries

Netherlands

# Eligibility criteria

**Age**
Children (2-11 years)

## Inclusion criteria

- Healthy children, i.e. no congentical / neurological disorders
- Age-matched with clubfootpatients (3-8 years)

### Exclusion criteria

- Children who are not able to understand and follow-up instructions
- Children who are not able to perform tasks (e.g. concentration problems)
- Obese children (BMI > 30)

## Study design

### Design

**Study type:** Observational non invasive

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

### Recruitment

NL

| | |
|---|---|
| Recruitment status: | Recruitment stopped |
| Start date (anticipated): | 18-03-2016 |
| Enrollment: | 50 |
| Type: | Actual |

## Ethics review

| | |
|---|---|
| Approved WMO Date: | 09-10-2015 |
| Application type: | First submission |
| Review commission: | MEC-U: Medical Research Ethics Committees United (Nieuwegein) |
| Approved WMO Date: | 09-08-2016 |
| Application type: | Amendment |

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| Review commission: | MEC-U: Medical Research Ethics Committees United (Nieuwegein) |
| Approved WMO Date: | 31-01-2018 |
| Application type: | Amendment |
| Review commission: | MEC-U: Medical Research Ethics Committees United (Nieuwegein) |
| Approved WMO Date: | 02-01-2019 |
| Application type: | Amendment |
| Review commission: | MEC-U: Medical Research Ethics Committees United (Nieuwegein) |

# 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 | NL53229.100.15 |