

# Part 1. Gait analysis in typically developed children: Differences in gait and balance characteristics during self paced gait between over ground VICON 3D motion capture system and the CAREN system.

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To compare gait and balance measured by the traditional 3D gait analysis system (VICON) and by the new system including a treadmill and a virtual environment (CAREN) during self-paced walking in typically developed children. In addition, a...

<b>Ethical review</b>	Approved WMO
<b>Status</b>	Recruitment stopped
<b>Health condition type</b>	Musculoskeletal and connective tissue disorders congenital
<b>Study type</b>	Observational non invasive

## Summary

### ID

NL-OMON45072

### Source

ToetsingOnline

### Brief title

Gait analysis in typically developed children.

### Condition

- Musculoskeletal and connective tissue disorders congenital

### Synonym

typically developed children

### Research involving



Human

## Sponsors and support

**Primary sponsor:** Academisch Medisch Centrum

**Source(s) of monetary or material Support:** Ministerie van OC&W

## Intervention

**Keyword:** Caren, children, Gait, vicon 3D

## Outcome measures

### Primary outcome

First, gait characteristics as such spatiotemporal parameters (e.g. step length), 3D kinematics and kinetics of the ankle, knee and hip joint, dynamic balance parameters (e.g. margins of stability, gait variability) and muscle activity will be determined by using both gait analysis systems. Second, reference values for gait and balance parameters of typically developed children of varying age will be created (and corrected for anthropomorphic variation).

### Secondary outcome

Second reference values for gait and balance parameters of typically developed children of varying age will be created.

## Study description

### Background summary

Threedimensional gait analysis is routinely used in regular evaluation and planning of treatment of children with mobility problems such as cerebral palsy and spina bifida. It has been shown that children with CP have to deal with high variability in trunk balance [34]. This variability in trunk balance demands extra effort and energy consumption. Abnormal fatiguing during walking



and falling is a major problem in these affected children. A stable gait pattern is thus essential, as it provides an efficient energy consumption (less fatigued) and it reduces the chance to fall.

The traditional gait analysis system (VICON 3D motion capture system) uses self-paced overground walking. Recently, a new system has become available at MUMC+; Computer Assisted Rehabilitation Environment (CAREN), which combines the VICON 3D motion capture system with a split belt treadmill and a virtual reality environment. This system enables to analyse several successive steps. In addition CAREN allows us to give real time feedback, providing and provides various training possibilities (e.i. gaming), which makes it attractive for children. For these reasons, we like to use CARENaren for gait analysis in children with mobility problems.

Only few studies are done comparing both systems, showing small differences in gait. However most of these studies focused on adults, and studies withon children are scarce.

## **Study objective**

To compare gait and balance measured by the traditional 3D gait analysis system (VICON) and by the new system including a treadmill and a virtual environment (CAREN) during self- paced walking in typically developed children. In addition, a reference database for gait and balance characteristics of typically developed children of different age ranges is created for both systems, which will be used to interpret deviations in gait of children with cerebral pareses and spina bifida.

## **Study design**

A comparative , cross- sectional properspective, single center pilot study on typically developed children of different ages. The composed age groups are based on known gait development phases throughout childhood. In each age group (3-4 years, 5-6 years, 7-8 years, 9-10 years, 11-12 years, 13 years and older) 10 children will be included. The choice for these age ranges and the amount subjects relies on several assumptions: The walking speed increases in children with 10% per 2 years. Literature shows that a sample size of 10 children per age range provides reproducible outcomes. In addition, the number of participants is matched with the availability of the VICON lab and the CAREN lab.

Inclusion criteria: ambulatory, ability to walk without aid for 60 minutes and age between 3-14 years.

Exclusion criteria: Acute and/or chronic muscular skeletal disorders, interventions such as surgical treatment or botulinum toxin 6 months prior to the assessment, severerious pes plano valgus, leg length difference > 1cm, scoliosise with Cobbse angle >10°, parents or caregivers who are not proficient



in the Dutch language.

### **Study burden and risks**

The risk of gait analysis is negligible. During the CAREN measurement, a safety harness is worn which provides protection against falling. The safety harness is secured with a life-line to the ceiling. The burden for the children is minimal. There is however a time burden. From start till end the whole analysis will take approximately 2 hours. Parents will receive compensation for travelling expenses. The children will receive a present (+/- 5 euros) for participation.

## **Contacts**

### **Public**

Academisch Medisch Centrum

P.debyelaan 25  
Maastricht 6229 HX  
NL

### **Scientific**

Academisch Medisch Centrum

P.debyelaan 25  
Maastricht 6229 HX  
NL

## **Trial sites**

### **Listed location countries**

Netherlands

## **Eligibility criteria**

### **Age**

Adolescents (12-15 years)  
Adolescents (16-17 years)  
Children (2-11 years)



## Inclusion criteria

- Ambulatory
- Ability to walk without aid for 60 minutes
- Age between 3-14 years
- Parents or caregivers and subject who are proficient in the Dutch language
- Willing to participate (permission from parents/care givers and subject);\* Age 3-14 years;
- \* Willing to participate (permission from parents/care giver)

## Exclusion criteria

A potential subject who meets any of the following criteria will be excluded from participation in this study:

- Acute and/or chronic muscular skeletal disorder
- Interventions, such as surgical treatment or botulinum toxin 6 months prior to the assessment
- Rigid or painful pes plano valgus
- Leg length difference > 1cm (block testing)
- Clinically manifest scoliosis (curved spinal column, unequal shoulder levels, gibbus deformity when bending)

## 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): 17-07-2017

Enrollment: 60

Type: Actual



## Medical products/devices used

Generic name: vicon 3d motek caren  
Registration: Yes - CE intended use

## Ethics review

Approved WMO  
Date: 20-07-2016  
Application type: First submission  
Review commission: METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)

## 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	NL51929.068.14