Validity of V-Gait analysis in children with cerebral palsy

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Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Congenital and peripartum neurological conditions
Study type	Observational non invasive

Summary

ID

NL-OMON37448

Source
ToetsingOnline

Brief title
V-Gait CP

Condition

- Congenital and peripartum neurological conditions

Synonym
brain lesion, cerebral palsy, spasticity

Research involving
Human

Sponsors and support

Primary sponsor: Vrije Universiteit Medisch Centrum
Source(s) of monetary or material Support: Ministerie van OC&W,Bedrijf: Motek Medical BV,Motek Medical BV

Intervention

Keyword: biomechanics, cerebral palsy, gait, treadmill test

Outcome measures

Primary outcome

The main study parameters are spatiotemporal variables, kinematics and kinetics during gait.

Secondary outcome

The secondary study parameter is subjective experience of the subjects in the different conditions.

Study description

Background summary

Gait analysis is a frequently used tool to precisely assess the gait-pattern deviations in children with Cerebral Palsy (CP). Gait analysis is typically performed in a gait laboratory in which a patient walks up and down a 5 to 10 meter walkway while muscle activity, kinetic and kinematic data are collected. Although valuable data are collected during an overground gait analysis, there are limitations. Only a few steps can be measured because patients need to speed up and slow down, and patients only have a few chances to hit the force plate. The new V-Gait system, based on treadmill, allows for continuous measurement during walking which makes it possible to take many steps per trial. The V-Gait system could thus potentially replace the gait lab while decreasing patients load and greatly enhancing the number of possible applications.

Study objective

The primary objective of this study is to determine whether 3D kinematics, kinetics and spatiotemporal parameters during walking on the V-Gait system are comparable to overground walking in children with cerebral palsy and in healthy children between the age of 8-16 years.
Secondary objectives are to determine the necessity of the V-Gait components: self-paced speed and virtual reality on gait parameters; and to determine whether the effect of V-Gait walking is different in children with CP compared

to typically developing children.

Study design

This is a Cross-sectional experimental study. The measurements will be performed in the gait laboratory of the VU Medical Centre in Amsterdam.

Study burden and risks

The study is carried out with minors. They will be asked to walk overground in the gait laboratory and on a treadmill with a virtual reality screen around them. The burden is minimal and the risks negligible because the overground walking as performed in the gait laboratory is identical to standard clinical tests as routinely performed. While walking on the V-Gait system, they are kept in a safety harness to remove the minimal risk of falling or stumbling off the treadmill. In a 2 hour session the subjects have to walk for a total of ~30 minutes, interrupted by resting pauses. Only children will be selected that are capable of doing so, so that the measurements will not impose any burden more than regular daily-life activities.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

All children with CP:
- must have a clinical diagnosis of CP,
- are aged between 8 and 16 years,
- are diplegic or hemiplegic,
- are able to walk independently without walking aids (GCMAS level I-II. gross motor function classification system, (Wood and Rosenbaum, 2000)),
- are able to walk (shod, with AFO if needed) for a total of at least 30 minutes in a 2h time span and 5 minutes on end,
- and can be both male or female;All typically developing children:
- are age matched and sex matched with the CP children.

Exclusion criteria

Children with CP will be excluded when:
- multilevel surgery has taken place less than 1 year prior participation,
- SDR or intrathecale baclophen (ITB) treatment has taken place less than 1 year prior to participation
- a BTX-A treatment has been given less than 16 weeks prior participation,
- the child*s movement pattern is mainly dyskinetic / ataxic,
- there are additional disorders (other than CP) that influence gait or
- parents or guardians and child do not understand the Dutch or English language well enough to take part in this project

Typically developing children will be excluded when:
- there are any (known) deviations that may influence gait or
- parents or guardians and child do not understand the Dutch or English language well enough to take part in this project.

Study design

Design

Study type:	Observational non invasive
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	18-06-2012
Enrollment:	20
Type:	Actual

Medical products/devices used

Generic name:	V-Gait
Registration:	Yes - CE intended use

Ethics review

Approved WMO Date:	22-05-2012
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	28-01-2013
Application type:	Amendment
Review commission:	METC Amsterdam UMC

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	NL38838.029.11