Gait analysis using inertial and magnetic sensors 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-OMON33329

Source
ToetsingOnline

Brief title
Outside-lab gait analysis using IMMS (OutwalkCP)

Condition

- Congenital and peripartum neurological conditions

Synonym
Brain damage, Cerebral Palsy, Spasticity

Research involving
Human

Sponsors and support

Primary sponsor: Vrije Universiteit Medisch Centrum
Source(s) of monetary or material Support: Het onderzoek is deel van het FreeMotion project;gefinancierd door het Ministerie van Economische Zaken en Senter Novem

Intervention

Keyword: Cerebral palsy, Gait analysis, Inertial and magnetic sensors

Outcome measures

Primary outcome

The main outcome product of the study is the refined protocol to achieve GA

from the IMMS for children with CP. The main measure is the difference in joint

kinematics, measured with the ambulatory system versus the reference

optoelectronic system, expressed in the Root Mean Square difference (RMSd) and

the coefficient of multiple correlation (CMC). The results will be published.

Secondary outcome

Secondary study parameters are

* the study of the reliability of the protocol developed.

* the study of the influence of a laboratory setting on the spontaneous walk of

the patient

Study description

Background summary

Cerebral Palsy (CP) is the problem of greatest interest among all child motor disabilities.
Gait Analysis (GA) is nowadays considered as the most refined tool available for the documentation
and the functional assessment of the gait, especially in CP children. The GA is widely used to classify
different forms of CP and to evaluate the effectiveness of rehabilitation treatments. Optoelectronic
measurements systems are currently the only systems used to obtain GA. However, such specialized
equipment limits the clinical use of this exam only to dedicated laboratory. Alternatively, an inertial and

magnetic measurement system (IMMS) can be used. Such systems are increasingly relevant in
clinical practice but need to be validated on CP children.

Study objective

The aims of the study are 1) to upgrade an existing GA protocol based on inertial system
(developed at the INAIL Prostheses Centre in collaboration with the University of Bologna) in terms of
finding out which calibration procedures result suitable to the different kind of patients with CP, and 2)
to evaluate the validity and the reliability of this protocol with respect to a reference system and
protocol, in measuring joint kinematics during gait.

Study design

This is a pilot study. Walking trials and measurements will be performed partly in the gait laboratory of the VU University Medical Center in Amsterdam, the Netherlands, and partly into a edicated reserved area in the same location. 10 CP children will be measured in a first session using the IMMS and the reference optoelectronic system to calibrate the systems on the subject*s body; then they will be measured inside the laboratory to investigate the validity of hardware and protocol; thirdly, the children will be measured in the reserved area outside the laboratory to determine the influence on the gait patterns of the laboratory setting itself; and finally the calibration procedures will be executed once more inside the laboratory to determine the reliability of the protocol.

Study burden and risks

Patients will be asked to walk a 10m walkway and a 50m walkway at self-selected speed, wearing the IMMS sensors and marker clusters attached to the segments of the lower extremities. The measurements are non-invasive. Markers and inertial sensors have cables and may somehow increase the burden during the measurements compared to normal walking. During walking, pain and fatigue could occur, however, the risk of pain will be minimal. Patients can quit the measurements if pain will occur. The practical relevance of this study is that validation of the IMMS in a clinical situation may help to introduce such systems in clinical practice in order to increase the use of the GA technique and to simplify and improve its application in CP children.

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

Diagnose Cerebral Palsy (hemiplegic or diplegic)
Between 7 and 15 years of age
GMFCS classification I, II or III

Exclusion criteria

- inability to understand the task required
- inability to understand the Dutch, English or Italian language.

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):	30-06-2009
Enrollment:	10
Type:	Actual

Ethics review

Approved WMO

Application type:	First submission
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	NL27647.029.09