Model-Driven Paediatric European Digital Repository (MD-Paedigree)

Published: 11-08-2014
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The main goal of the VUmc part of the study is to acquire sets of data related to Neurological and Neuromuscular Diseases; in order to build a paediatric digital repository and to develop biophysical modelling and probabilistic modelling.

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

Summary

ID

NL-OMON42159

Source
ToetsingOnline

Brief title
MD-Paedigree

Condition

- Congenital and peripartum neurological conditions

Synonym
cerebral palsy; spastic children

Research involving
Human

Sponsors and support

Primary sponsor: Vrije Universiteit Medisch Centrum
Source(s) of monetary or material Support: Europese Unie

Intervention

Keyword: Cerebral Palsy, Clinical Gait Analysis, Musculoskeletal Modelling, Probabilistic Modelling

Outcome measures

Primary outcome

For both standard care group and extended measurement group: Standardized history; 3D Clinical gait analysis (kinematic data; kinetic data; EMG); Walking oxygen consumption data; and Standard physical exam. For the extended measurement group only: isometric muscle strength; lower body MRI of bones and lean tissue. For TD children: 3D clinical gait analysis; for some TD children also other measurements of the extended protocol.

Secondary outcome

not applicable

Study description

Background summary

The EU-funded FP7 project MD-Paedigree aims to create a large-scale European database for four paediatric disease areas. This database will consist of clinical data and biophysical modelling outcomes. Biophysical modelling aims to unravel the pathophysiology of the various diseases. The large database will allow statistical modelling on large numbers of patients, to allow similarity searches and individualized treatment prediction.

Study objective

The main goal of the VUmc part of the study is to acquire sets of data related to Neurological and Neuromuscular Diseases; in order to build a paediatric digital repository and to develop biophysical modelling and probabilistic modelling.

Study design

Translational study

Study burden and risks

The measurement will take approximately 5 hours of which 2.5 hours are due to the extra measurements for the extended group. All measurements will be performed within one day if possible. If necessary for logistic reasons or if preferred by the patient and parents/guardians the measurements can be split into two separate sessions, one at the dept. of rehabilitation medicine and one at the dept. of radiology, with a maximum of one week in between the two sessions. The measurements will be combined with standard clinical care measurements, if possible. The actual MRI measurement will take approximately 3 times 7 minutes scan time.Lying still for this amount of time might be burdensome for some 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

- Aged between 6 and 15 years (8-15 for the extended measurements for CP children)
- Parent/guardian consent
- Sufficient cognitive skills: able to follow simple instructions;For patient group only:
- Children with a diagnosis of Cerebral Palsy following the definition of Rosenbaum: *Cerebral Palsy (CP) describes a group of permanent disorders of the development of movement and posture, causing activity limitation, that are attributed to non progressive disturbances that occurred in the developing foetal or infant brain. The motor disorders of cerebral palsy are often accompanied by disturbances of sensation, perception, cognition, communication, and behaviour, by epilepsy, and by secondary musculoskeletal problems*
- GMFCS level I-II. (gross motor function classification system)
- Spastic cerebral palsy

Exclusion criteria

- Patient history of functional surgery on bones and/or muscles of the legs; selective dorsal rhizotomy (not during follow up for the standard usual care group)
- Lower limbs BoNT A injection in the last 6 months (not during follow up for the standard usual care group)
- Patient history of hip, backbone and/or lower limb fracture;
- Relevant visual deficit;
- Behavioural problems of an extent that they can impede normal subject cooperation
- Significant comorbidities
- Claustrophobia.
- A pacemaker or other non-removable metal-containing devices or objects
- Not able to lie still for 3 times 7 minutes
- Not willing to hear about *incidental findings*, potential unforeseen, clinically relevant abnormalities found in the MRI images.

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):	22-01-2015
Enrollment:	30
Type:	Actual

Ethics review

Approved WMO

Date:	11-08-2014
Application type:	First submission
Review commission:	METC Amsterdam UMC

Approved WMO

Date:	26-01-2015
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	NL48494.029.14