Protocol optimization of the quantificaion of gait using the GAITRIte in children with mitochondrial disease

Published: 12-09-2016
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The aim of this study is to optimize the protocol for gait analysis for children with mitochondrial diseasesSecundary- feasibility- reliability- reliability after exercise- compare with healthy controls- reference values for children

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Metabolic and nutritional disorders congenital
Study type	Observational non invasive

Summary

ID

NL-OMON43067

Source
ToetsingOnline

Brief title
GAITRite in children with mitochondrial disease

Condition

- Metabolic and nutritional disorders congenital

Synonym
energy metabolism abnormalities

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum
Source(s) of monetary or material Support: Zeldzame ziekten fonds

Intervention

Keyword: Children, Gait, Mitochondrial disease, Outcome measure

Outcome measures

Primary outcome

Parameters of gait

Secondary outcome

3 minute walking distance

Study description

Background summary

Gait is an emerging end point for clinical studies, which will be used in a phase 2 trial in adults at our centre. To prepare for future paediatric studies, we aim to determine whether gait, measured by the GAITRite is also a feasible and reliable end point for children.

Study objective

The aim of this study is to optimize the protocol for gait analysis for children with mitochondrial diseases

Secundary
- feasibility
- reliability
- reliability after exercise
- compare with healthy controls
- reference values for children

Study design

OBservational study

Study burden and risks

The test is not burdensome and combined with an outpatient visit. Precautions are taken when the child has a high likelihood of falls

Contacts

Public
Selecteer

Geert grooteplein noord 10
Nijmegen 6500 HB
NL
Scientific
Selecteer

Geert grooteplein noord 10
Nijmegen 6500 HB
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

Patients:
- aged 1-18 years
- genetically confirmed mitochondrial disease
- able to walk 3x10 meters; five times;Healthy controls
Aged 1-18 years
able to walk
no neurological, orthopedic or neuromuscular disease influencing gait

Exclusion criteria

- Ernstige gedragsproblemen

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:	Other

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-10-2016
Enrollment:	218
Type:	Actual

Ethics review

Approved WMO Date:	12-09-2016
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	18-10-2016
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	25-01-2017

Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)

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	NL58062.091.16