The feasibility, reliability and validity of the MOX-accelerometer in measuring daily physical endurance in children with a mitochondrial disorder

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In this study, we aim to test the feasibilty, reliability and validity of the MOX-accelerometer in measuring daily physical activity in children with mitochondrial disease.

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

Summary

ID

NL-OMON40669

Source
ToetsingOnline

Brief title
The MOX-accelerometer in children with a mitochondrial disorder

Condition

- Metabolic and nutritional disorders congenital

Synonym
mitochondrial encephalomyopathy, mitopathy

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Sint Radboud
Source(s) of monetary or material Support: ZonMW AGIKO S. Koene,Mogelijk

Stofwisselkracht (uitslag volgt 1-10-2014)

Intervention

Keyword: Accelerometer, Daily physical activity, Mitochondrial disease, Outcome measure

Outcome measures

Primary outcome

The feasibility (% of patients), reliability (test-retest, % of data) and

validity (correlation with video of standardized movements, correlation with

reported activities) of the MOX-accelerometer in children with a mitochondrial

disease

Secondary outcome

na

Study description

Background summary

More and more clinical studies are performed in patients with mitochondrial disorders, of which many in children. Children with mitochondrial disorders are often severely disabled and not able to follow commands. One of the major complaints of this patient group, is lack of energy and tiredness.

Study objective

In this study, we aim to test the feasibilty, reliability and validity of the MOX-accelerometer in measuring daily physical activity in children with mitochondrial disease.

Study design

Patients are asked to wear the accelerometer for two consequetive weekend days. The validity is tested by using a standardized protocol of movements and by correlating with the sort and intensity of activities, as reported by parents. Parents are asked to fill out a diary during the weekend, reporting the sort of activity, and the subjective activity and wellbeing of the patient.

We will include both patients and healthy controls to be able to express the activity as a percentage of the healthy population.

Study burden and risks

In our previous study in patients with Leigh syndrome, no complications of wearing the MOX-accelerometer were reported. We cannot think of risks of wearing the accelerometers other than decubitus (which will always be limited since the meters are worn only for one weekend and they should be removed in case any redness of the skin appears). The burden is mainly an administrative burden to parents.
For the group of children with mitochondrial disease as a whole, and maybe even for other diseases with severe disabilities, this is a valuable study in chosing outcome measures for future clinical trials based on experience.

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

Patients:
- aged 4-18 years
- decreased ATP production in fresh muscle (to same extend as descrease in pyruvateoxidation rate) or mutation in gene known to cause mitochondrial disease
- follow-up in NCMD;Heatlhy controls
- Healthy
- Regular education
- Aged 4-18 years

Exclusion criteria

Patients:
- Fever
- Epilepsia continua
- Altered state of conciousness compared to normal;Healthy controls:
- Regularly seen by a paediatrician
- Complaints of exercise intolerance, muscle complaints or fatigue, more than peers
- Official ADHD diagnosis
- Sibling with neuromuscular or metabolic disease

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:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-02-2015
Enrollment:	50
Type:	Actual

Ethics review

Approved WMO Date:	10-02-2015
Application type:	First submission
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	NL50560.091.14