

# 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 feasibility, reliability and validity of the MOX-accelerometer in measuring daily physical activity in children with mitochondrial disease.

<b>Ethical review</b>	Approved WMO
<b>Status</b>	Recruitment stopped
<b>Health condition type</b>	Metabolic and nutritional disorders congenital
<b>Study type</b>	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

## 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 feasibility, 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 consecutive 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 choosing 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 decrease in pyruvateoxidation rate) or mutation in gene known to cause mitochondrial disease
- follow-up in NCMD; Healthy controls
- Healthy
- Regular education
- Aged 4-18 years

## Exclusion criteria

Patients:

- Fever
- Epilepsia continua
- Altered state of consciousness 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