Exploring the feasibility, reliability and validity of the Xsens 3D movement detector for measuring daily physical activity in patients with Leigh syndrome.

Published: 11-04-2013
Last updated: 25-04-2024

The aim of this study is to assess the feasibility, reliability and validity of the Xsens 3D motion detector in patients with Leigh syndrome.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Other condition
Study type	Observational non invasive

Summary

ID

NL-OMON40100

Source
ToetsingOnline

Brief title
The Xsens 3D movement detector in children with Leigh syndrome.

Condition

- Other condition

Synonym
mitochondrial disease, mitochondrial disorder

Health condition

mitochondriele aandoeningen

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Sint Radboud
Source(s) of monetary or material Support: ZonMW AGIKO,Energy4all

Intervention

Keyword: 3D movementdetector, accelerometer, Leigh syndrome, Outcome measure

Outcome measures

Primary outcome

1. To determine the feasibility, reliability and validity of the Xsens 3D

motion detector for measuring daily activity in children with mitochondrial

disease and severe mental and / or physical disabilities.

a) Feasibility for measuring for 2 days

b) Reliability: for how many percent of the time does the Xsens 3D motion

detector obtain reliable data?

c) Validity:

o Agreement between Xsens data and the standardized

movements (if possible by means of the GMFM) for 30 minutes

o Correlation between Xsens data and activity reported by

the parents (reported on a scale of 0 to 10 every hour) for 1 weekend

Secondary outcome

1. Patterns in the frequency, duration, type and intensity of movements in

patients with Leigh syndrome

2. Patterns of movements in spasticity and various movement disorders

3. Testing the feasibility of the GMFM, Tardieu and MDRS

4. Get an indication of the frequency, duration, type and intensity of

movements related to how the patient feels.

Study description

Background summary

Mitochondrial disorders are the most common metabolic diseases that manifest with disturbances in energy production. This leads to tiredness and exercise intolerance in less affected patients and to a modified lifestyle with lots of rest and low activity in more affected patients. Since more and more clinical research is done in this disease, in particular in patients who are severely affected, good outcome measures are of great importance. However, because many of these patients are both physically and mentally severely disabled and sometimes have problems with interaction, this is a challenge!
This pilot study explores a method to measure "exercise tolerance" (the ability to maintain daily activities or the balance between rest and activity during the day) in children who are severely mentally or physically limited.
We want to measure this with the Xsens 3D accelerometer. This is a 3-dimensional motion detector, which is able to measures the duration, frequency, intensity and type of movement. The 3-dimensional motion detector was able to estimate the level of activity in patients with Duchenne.
We expect that Xsens 3D motion detector will be able to measure physical activity / fitness in patients with Leigh syndrome.

Study objective

The aim of this study is to assess the feasibility, reliability and validity of the Xsens 3D motion detector in patients with Leigh syndrome.

Study design

This is an observational pilot study without invasive measurements.

Study burden and risks

We don't expect major risks in this pilot study. The burden is mainly a time burden.

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 0-18 years
- With on the MRI Leigh or Leigh-like syndrome
- And mitochondrial dysfunction in biochemical analysis of fresh muscle
- Who are regularly monitored in the Nijmegen Centre for Mitochondrial Disorders.

Exclusion criteria

It is expected that the trip to the hospital is too burdensome for the patient.
Fever
Epilepsia continua
Altered consiousness (according to parents/caretakers)

Study design

Design

Study type: Observational non invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-04-2015
Enrollment:	7
Type:	Actual

Ethics review

Approved WMO

Date:	11-04-2013
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	NL42508.091.12