Function and body composition of patients with mitochondrial disease

Published: 31-08-2016
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1. Determine body composition of MD patients;2. Determine physical function of MD patients;3. Determine the association of body composition and physical function of MD patients.

Ethical review	Approved WMO
Status	Completed
Health condition type	Inborn errors of metabolism
Study type	Observational non invasive

Summary

ID

NL-OMON43364

Source
ToetsingOnline

Brief title
DYNAMO

Condition

- Inborn errors of metabolism

Synonym
disorder of mitochondrial metabolism, mitochondrial disease

Research involving
Human

Sponsors and support

Primary sponsor: Radboud Universitair Medisch Centrum
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: body composition, function, mitochondrial disease

Outcome measures

Primary outcome

physical function (hand grip strength)

Secondary outcome

Physical function (30 sec sit-to-stand, 6 minute walking test, 6 minute chew

test), body composition (BMI, fat(free)mass, muscle mass);

Other parameters: nutritional intake (energy, macro- en micronutrients),

nutritional status

Study description

Background summary

Patients with mitochondrial disease (MD) experience, because of a disorder in the intracellular energy generation, a variety of complaints such as muscle pain, swallowing complaints, endurance intolerance. Treatment of these patients is mainly supportive for remaining functionality and quality of life. Patients with other neuromuscular diseases express a diminished physical functioning with changes in body composition, e.g. decreased muscle mass and an increase in fat mass. It is yet not known whether patients with mitochondrial disease experience similar symptoms.
Our hypothesis is that patients with mitochondrial disease have changes in body composition and that they have decreased physical function compared with healthy control subjects. If this is the case, improvement of body composition may be a goal of the treatment (dietary) intervention.

Study objective

1. Determine body composition of MD patients;
2. Determine physical function of MD patients;
3. Determine the association of body composition and physical function of MD

patients.

Study design

An observational, cross-sectional study to determine the association between body composition and physical function in MD patients as compared with matched healthy controls (matched for age, gender and BMI). Physical function and body composition will be measured once after an overnight fast. Nutritional intake and nutritional status will be assessed, as these factors may influence body composition as well as physical function. All parameters will be assessed according to the usual care procedures for MD patients in the "Mitostraat" (Radboud Centre for Mitochondrial Medicine). Parameters of the healthy controls will be assessed identically at the Nutritional Assessment Lab at the HAN University of Applied Sciences.

Study burden and risks

The risk is low. The measurements of body composition, physical function and nutritional intake are part of usual care for large groups of patients and is considered safe. The burden for healthy volunteers consists of one visit of about two hours for measurements at the HAN, being fasted, the measurements itself, registration of nutritional intake during three days in advance of the visit and the DEXA scan. None of the measurements are invasive. Patients will be measured in the hospital during their usual care before breakfast.

Advantages: individual questions on nutrition, body composition and physical function may be answered by the investigator. Also, MD patients will receive extra attention and information on their nutritional status and functioning. Healthy controls will receive a report on their physical function, body composition and nutritional status. In case of odd outcomes for healthy controls may this will be noted in the report and the individual will, when relevant, be referred to a physician.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

• Age >= 18 jaar;
• Admitted to Mitostraat (alleen patiënten);
• Signed informed consent.

Exclusion criteria

• Pacemaker or implant;
• Pregnant or lactating;
• Abnormal hydration status (oedema, dehydration);
• Diagnosed for a (chronic) disease interfering with nutritional assessment (only for healthy controls);

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:	Completed
Start date (anticipated):	21-12-2016
Enrollment:	74
Type:	Actual

Ethics review

Approved WMO

Date:	31-08-2016
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	NL58262.091.16

Study results

Date completed:	09-05-2018
Results posted:	07-04-2020
Actual enrolment:	74

URL result
URL
Type
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Naam
doi.org
URL
Type
int
Naam
M2.2 Samenvatting voor de leek
URL

Internal documents
File