a explorative study of nutritional state and the effect of diet intervention on body composition, muscle strength, activity, pulmonary function and quality of life in adults with mitochondrial disease caused by the m.3243A.G mutation.

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1. To obtain knowledge about the nutritional status of adult patients with mitochondrial disease and the determinants that contribute to this.2. Evaluate the effect of dietary intervention in adult patients with mitochondrial disease on nutritional...

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

Summary

ID

NL-OMON39342

Source
ToetsingOnline

Brief title
Nutritional state and effect of diet intervention in mitochondrial disease

Condition

- Metabolic and nutritional disorders congenital
- Inborn errors of metabolism

Synonym

m. 3243A.G mutation, MELAS, MIDD, Mitochondrial disease, OXPHOS deffect

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Sint Radboud
Source(s) of monetary or material Support: subsidie nog niet toegezegd wordt wel naar gezocht

Intervention

Keyword: Adult, Mitochondrial disease, Nutritional State

Outcome measures

Primary outcome

nutritional status.

Secondary outcome

activity, lung function, hand grip strength, body composition, food intake,

fatigue and quality of life.

Study description

Background summary

The m.3243A> G mutation is the most frequent cause of mitochondrial disease in adults. For a mitochondrial disease no therapy is available. The treatment is supportive, aiming to improve quality of life. Clinical findings in patients with mitochondrial diseases are both malnutrition and obesity. A nutritional intervention could be a symptomatic treatment for these patients.

Study objective

1. To obtain knowledge about the nutritional status of adult patients with mitochondrial disease and the determinants that contribute to this.
2. Evaluate the effect of dietary intervention in adult patients with mitochondrial disease on nutritional status, pulmonary function, muscle strength, activity, fatigue and quality of life.
3. To create referral criteria for dietary intervention in patients with

mitochondrial diseases.

Study design

Part 1 consists of descriptive research using an extensive Nutritional Assessment (NA) with indirect calorimetry (IC), bioimpedance analysis (BIA), anthropometry, eating and activity report, activity measurement using the actometer, completing questionnaires and pulmonary function tests.
Part 2 is a randomised controlled intervention study which 2 study groups. One starts with diet intervention and the other starts with a control period of 6 months. After this period the second group also starts with the diet intervention. This includes optimizing the diet based on individually calculated energy and protein requirements and for the other nutrients the recommended daily amounts (RDA) are followed. Nutritional Assessment measurements will be repeated every 3 months. Indirect Calorimetry only one at the beginning and pulmonary function every 6 months.

Intervention

diet intervention individualy calculated for energy and protein other nutrients according to the RDA

Study burden and risks

Low risk, risk of fasting are evaluated by physician and only when it is safe for patients they can enter the study. The protein requirement is individually calculated, which rules out additional risk for patients with any renal impairment. Some burden: 3-5 clinic visits of approximately 2 hours in which patients should be fasting for Nutritional Assessment, 4 x 3 days keeping food and activity report and carry actometre, 3-5 x questionnaires, 2-3 x pulmonary function tests (visits 1,3 and 5). The dietary intervention may also be experienced as a burden.
It might be positive that the individual questions about nutrition can be answered, patients get attention and are properly checked and that they can benefit from the intervention.-

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

Proven mitochondrial m. 3243A>G mutation
age > 18 years
No medical contra indication for reseaving Nutritional assesment in sober state.
informed consent

Exclusion criteria

sober state is contra indicated for medical reasons, for exemple to high risk for hypoglycemia
pacemaker, any implantations made from metal
claustrophobia
no informed consent

Study design

Design

Study type: Interventional

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	06-03-2014
Enrollment:	50
Type:	Actual

Ethics review

Approved WMO

Date:	18-06-2013
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	NL39724.091.13