Influence of individual diet and physiotherapy intervention on the outcome of mitochondrial disease

Published: 28-12-2009
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To improve the quality of life and physical condition of children with mitochondrial disease.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Other condition
Study type	Interventional

Summary

ID

NL-OMON31561

Source
ToetsingOnline

Brief title
Influence of diet and physiotherapy on outcome of mitochondrial disease

Condition

- Other condition

Synonym
mitochondrial myopathy

Health condition

mitochondriele aandoeningen

Research involving
Human

Sponsors and support

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

Intervention

Keyword: diet intervention, mitochondrial disease, outcome, physiotherapy

Outcome measures

Primary outcome

Quality of life and a better physical - and feeding condition.

Secondary outcome

nvt

Study description

Background summary

We assume that nutritional intervention with an individualized diet and optimal dietary intake in children with a mitochondrial disease supported by aerobic conditional training improves the energy generating capacity, the clinical condition and the quality of life in patients.

Study objective

To improve the quality of life and physical condition of children with mitochondrial disease.

Study design

We will prospectively evaluate and follow up the clinical features, biochemical characteristics, neuro-imaging and neurophysiological findings, motor development, exercise tolerance, dietary intake, nutritional state, anthropometric parameters, energy expenditure, respiratory quotient and the histological and biochemical findings in muscle in all children. We will evaluate the state of health, psychomotor development, level of fatigue, clinical progression and the quality of life with appropriate validated clinical questionnaires. After detailed evaluation we will offer nutritional

intervention and advise for physiotherapy and general activity including an individualized exercise program for children with exercise intolerance for the second half year. Over a year all evaluations will be repeated except for the muscle biopsy.

Intervention

A individual diet
Aerobic physiotherapy

Study burden and risks

The patients may benefit from new insights in energy metabolism of mitochondrial diseases.

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

MDC-score > 5 (zie protocol pag 2)

Exclusion criteria

MDC-score < 5 (zie protocol pag 2)

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):	01-06-2008
Enrollment:	50
Type:	Anticipated

Medical products/devices used

Registration:	No

Ethics review

Approved WMO

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	NL21241.091.07