Beneficial effect of beetroot or spinaze consumption in mitochondrial myopathy patients.

No registrations found.

Ethical review	Positive opinion
Status	Pending
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON26686

Source
Nationaal Trial Register

Health condition

mitochondrial myopathy

Sponsors and support

Primary sponsor: Eindhoven University of Technology
Erasmus Medical Center
Maxima Medical Center
Univerisity Medical Centre Maastricht
University Medical Center Groningen
Source(s) of monetary or material Support: fund = initiator = sponsor

Intervention

Outcome measures

Primary outcome

1. Steady state oxygen consumption at 50%Wmax;

2. In vivo mitochondrial function (31P MRS);

3. In vitro mitochondrial function (state 3, 4, U respiration).

Secondary outcome

1. mtDNA copy number;

2. C1, C2, C3, C4, F1F0ATPase, ANT content;

3. Muscle fiber type composition.

Study description

Background summary

The objective of the study is to test if supplementation of dietary inorganic nitrate (8.5 mg/kg body wt/day) to normal diet improves exercise performance in patients with mitochondrial myopathy. The main study parameters to asses the effect of nitrate intake will be: (i) steady state oxygen consumption at 50%Wmax, (ii)
in vivo mitochondrial function (31P MRS), (iii)
in vitro mitochondrial function (state 3, 4, U respiration).

Study objective

Dietary inorganic nitrate supplementation will decrease O2 cost of exercise in patients with mitochondrial myopathy.

Study design

Day 1 and day 8.

Intervention

8 days dietary inorganic nitrate supplementation (sodium nitrate 8.5mg/kg body wt/day dissolved in 250 ml water).

Contacts

Public

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Eligibility criteria

Inclusion criteria

1. Diagnosis mitochondrial myopathy;

2. Age 18+.

Exclusion criteria

1. Pacemaker / ICS or other contra indication for MRI;

2. Claustrophobia;

3. Use of beta blocker therapy;

4. Use of oral anti-coagulants;

5. Use of aspirine NSAID's;

6. Use of calcium antagonists;

7. Use of inorganic nitrate;

8. Cardio-vascular disease;

9. Cerebro-vascular complications;

10. Neurological diseases of deficits;

11. Vascular complications.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Non controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	15-03-2012
Enrollment:	10
Type:	Anticipated

Ethics review

Positive opinion

Date:	23-02-2012
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 39110
Bron: ToetsingOnline
Titel:

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
NTR-new	NL3177
NTR-old	NTR3321
CCMO	NL36927.015.11
ISRCTN	ISRCTN wordt niet meer aangevraagd.
OMON	NL-OMON39110

Study results

Summary results
N/A