Lowering of very long chain fatty acids in patients with X-linked adrenoleukodystrophy (X-ALD): A biochemical study.

No registrations found.

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

Summary

ID

NL-OMON22008

Source
NTR

Brief title
LOVA

Sponsors and support

Primary sponsor: Trial medication was provided by Merck, Sharp and Dome (MSD)

Source(s) of monetary or material Support: The study is supported by a grant from ELA (European Leukodystrophy Foundation)

Intervention

Outcome measures

Primary outcome

Very long chain fatty acid levels (in plasma and erythrocytes).

Study description

Background summary

In 1998 Singh et al reported that lovastatin (a cholesterol lowering drug) could reduce very long chain fatty acids in cultured skin fibroblasts from patients with X-ALD. A small open label study showed an effect on plasma VLCFA in some patients, a finding that was not reproduced in a small study with simvastatin. With this randomized double blind placebo controlled cross-over study we aim to systematically study the effect of lovastatin (or more generally cholesterol lowering) on very long chain fatty acids in X-ALD.

Study objective

Cholesterol lowering by low fat diet and lovastatin will also reduce very long chain fatty acids in patients with X-ALD.

Intervention

1. All patients participating in the trial will
comply to a diet (American Heart Association level 1).
2. All patients will receive 6 months of placebo and 6 months of lovastatin 40 mg
daily in random order (double blind, crossover design).

Contacts

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Eligibility criteria

Inclusion criteria

1. Male patients with X-ALD (confirmed by biochemical analysis or mutation analysis of the ABCD1 gene);
2. 18 years or older;
3. Able to give informed consent and visit the hospital;
4. No contraindications for use of trial medication.

Exclusion criteria

1. Use of another cholesterol lowering drug;
2. Liver disease or CK more than 3 times baseline level;
3. Use of very long chain fatty acid lowering therapy (e.g. Lorenzo's oil) in the 8 weeks preceding the study.

Study design

Design

Study type:	Interventional
Intervention model:	Crossover
Masking:	Double blinded (masking used)
Control:	Placebo

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-08-2006
Enrollment:	20
Type:	Anticipated

Ethics review

Positive opinion

Date:	06-04-2006
Application type:	First submission

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
NTR-new	NL623
NTR-old	NTR682
Other	: MEC05/175
ISRCTN	ISRCTN31565393

Study results

Summary results
N/A