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

Gepubliceerd: 06-04-2006 Laatst bijgewerkt: 13-12-2022

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

Ethische beoordeling	Positief advies
Status	Werving gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON22008

Bron
Nationaal Trial Register

Verkorte titel
LOVA

Ondersteuning

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

Overige ondersteuning: The study is supported by a grant from ELA (European Leukodystrophy Foundation)

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

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

Onderzoeksproduct en/of interventie

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).

Contactpersonen

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

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.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Cross-over
Blindering:	Dubbelblind
Controle:	Placebo

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	01-08-2006
Aantal proefpersonen:	20
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	06-04-2006
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL623
NTR-old	NTR682
Ander register	: MEC05/175
ISRCTN	ISRCTN31565393

Resultaten

Samenvatting resultaten
N/A