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Lowering Of Very long chain fatty Acids in patients with X-linked adrenoleukodystrophy: a biochemical study

Submission date 22/11/2006	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 22/11/2006	**Overall study status** Completed	
Last Edited 29/01/2010	**Condition category** Nervous System Diseases	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
MEC05/175; NTR682

Study information

Scientific Title

Acronym
LOVA

Study objectives
Cholesterol lowering by low fat diet and lovastatin will also reduce very long chain fatty acids in patients with X-linked adrenoleukodystrophy (X-ALD).

Ethics approval required
Old ethics approval format

Ethics approval(s)
Received from the local medical ethics committee

Study design
Randomised double-blind placebo controlled crossover trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Not specified

Study type(s)
Treatment

Participant information sheet

Health condition(s) or problem(s) studied
X-linked adrenoleukodystrophy (X-ALD)

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

Intervention Type
Drug

Phase
Not Specified

Drug/device/biological/vaccine name(s)

Lovastatin

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

Secondary outcome measures
No secondary outcome measures

Overall study start date
01/08/2006

Completion date
01/08/2008

Eligibility

Key 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

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Male

Target number of participants
20

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

Date of first enrolment
01/08/2006

Date of final enrolment
01/08/2008

Locations

Countries of recruitment
Netherlands

Study participating centre
Academic Medical Centre (AMC)
Amsterdam
Netherlands
1100 DD

Sponsor information

Organisation
Academic Medical Centre (AMC) (Netherlands)

Sponsor details
P.O. Box 22660
Amsterdam
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1100 DD

Sponsor type
Hospital/treatment centre

Website
http://www.amc.nl/

ROR
https://ror.org/03t4gr691

Funder(s)

Funder type
Research organisation

Funder Name
European Leukodystrophy Foundation (ELA)

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	21/01/2010		Yes	No