

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	<input type="checkbox"/> Prospectively registered
Registration date 22/11/2006	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 29/01/2010	Condition category Nervous System Diseases	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data

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

Netherlands

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