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

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

**Protocol serial number**
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

### Primary study design
Interventional

### Study design
Randomised double-blind placebo controlled crossover trial

### Study type(s)
Treatment

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

### Key secondary outcome(s)
No secondary outcome measures

### 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

### Healthy volunteers allowed
No

### Age group
Adult

### Lower age limit
18 Years

### Sex
Male

### 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)

**ROR**
https://ror.org/03t4gr691

# Funder(s)

**Funder type**
Research organisation

**Funder Name**
European Leukodystrophy Foundation (ELA)

# Results and Publications

## 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 |