

Ascorbic Acid Treatment in Charcot-Marie-Tooth Disease Type 1A (CMT1A) Trial

Submission date 22/11/2005	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 22/11/2005	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 18/12/2009	Condition category Nervous System Diseases	<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

Protocol serial number
N/A

Study information

Scientific Title

Acronym

AATIC

Study objectives

Ascorbic acid has been shown to have a favorable influence on myelination in in vitro studies and in a mouse model for CMT1A. We will study the efficacy and safety of ascorbic acid treatment in young patients with CMT1A.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Received from local medical ethics committee

Study design

Randomised double blind placebo controlled parallel group trial

Primary study design

Interventional

Study type(s)

Not Specified

Health condition(s) or problem(s) studied

Charcot-Marie-Tooth Disease Type 1A (CMT1A), Hereditary Motor and Sensory Neuropathies (HMSN Ia)

Interventions

Ascorbic acid 1000 mg (4 capsules of 250 mg) twice daily for one year or placebo in 4 capsules twice daily for one year

Intervention Type

Drug

Phase

Not Specified

Drug/device/biological/vaccine name(s)

Ascorbic acid

Primary outcome(s)

Change in motor nerve conduction velocity of the median nerve after 1 year

Key secondary outcome(s)

1. Change in minimal F response latency of the median nerve after 1 year
2. Changes in compound muscle action potential amplitude and area after 1 year
3. Change in motor unit number estimation of the abductor pollicis brevis muscle after 1 year
4. Changes in handgrip strength, strength of arm flexors, foot dorsiflexors, knee extensors and hip flexors after 1 year
5. Change in overall disability sum score after 1 year

6. Change in AMC Linear Disability Scale score after 1 year
7. Evaluation of serum ascorbic acid concentrations during 1 year
8. Evaluation of side effects during 1 year

Completion date

01/11/2007

Eligibility

Key inclusion criteria

1. DNA-proven CMT1A patients
2. Age 12-25 years
3. CMT1A patients with symptomatology defined as muscle weakness in at least foot dorsiflexion

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Other

Sex

All

Key exclusion criteria

1. Due to possible influence on severity of the neuropathy:
 - 1.1. Known other disease that may cause a neuropathy, that may decrease mobility, or that may lead to severe disability or death in a short time
 - 1.2. Medication that may cause a neuropathy
 - 1.3. Chronic alcohol abuse
2. Due to study medication (ascorbic acid):
 - 2.1. Regular use of vitamin C
 - 2.2. Clinical or echographic signs of nephrolithiasis
 - 2.3. Reduced glomerular filtration rate
 - 2.4. Iron overload
 - 2.5. No regular dental control at the dentist
 - 2.6. Pregnancy or active pregnancy wish for women
3. Due to study design and primary outcome:
 - 3.1. Not signing the informed consent
 - 3.2. Psychiatric co-morbidity which may influence compliance
 - 3.3. Not being comfortable during nerve conduction studies of the median nerve
 - 3.4. A too small Compound Muscle Action Potential (CMAP) amplitude of the abductor pollicis brevis muscle for a proper determination of the nerve conduction velocity of the median nerve

Date of first enrolment

01/11/2005

Date of final enrolment

01/11/2007

Locations

Countries of recruitment

Netherlands

Study participating centre

Academic Medical Center

Amsterdam

Netherlands

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Sponsor information

Organisation

Academic Medical Centre, Department of Neurology (Netherlands)

ROR

<https://ror.org/03t4gr691>

Funder(s)

Funder type

Hospital/treatment centre

Funder Name

Academic Medical Centre, Department of Neurology (Netherlands)

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				

[Results article](#)

12/11/2009

Yes

No