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

Submission date	Recruitment status
22/11/2005	No longer recruiting
Registration date	**Overall study status**
22/11/2005	Completed
Last Edited	**Condition category**
18/12/2009	Nervous System Diseases

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[X] Results
[ ] 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
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

Secondary study design
Randomised controlled trial

Study setting(s)
Not specified

Study type(s)
Not Specified

Participant information sheet

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

Secondary outcome measures
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 armflexors, 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

Overall study start date
01/11/2005

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

Age group
Other

Sex
Both

Target number of participants
12

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
-

Sponsor information

Organisation
Academic Medical Centre, Department of Neurology (Netherlands)

Sponsor details
P.O. Box 22660
Amsterdam
Netherlands
1100 DD

Sponsor type
University/education

Website
http://www.amc.nl/

ROR
https://ror.org/03t4gr691

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Academic Medical Centre, Department of Neurology (Netherlands)

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	12/11/2009		Yes	No