Tremor in demyelinating neuropathy, a study on the prevalence, etiology and characteristics of tremor in demyelinating neuropathy

Published: 22-08-2018
Last updated: 12-04-2024

The main study objective is to determine the prevalence of tremor in patients with neuropathy and describe the tremor characteristics.Secondary study objectives are: - To evaluate the functional disability and quality of life in patients with...

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Movement disorders (incl parkinsonism)
Study type	Observational invasive

Summary

ID

NL-OMON54557

Source
ToetsingOnline

Brief title
Tremor in demyelinating neuropathy

Condition

- Movement disorders (incl parkinsonism)

Synonym
tremor in demyelinating neuropathy; tremor associated with polyneuropathy

Research involving
Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum

Source(s) of monetary or material Support: het onderzoek wordt grotendeels budgetneutraal uitgevoerd aangezien de werkzaamheden worden verricht door personen al in dienst van het AMC of de AMR. Voor de kosten van de fMRI onderzoeken is een aanvullende financiering ter beschikking gesteld.

Intervention

Keyword: Demyelinating, Neuropathy, Polyneuropathy, Tremor

Outcome measures

Primary outcome

The main study parameters are the prevalence of tremor in demyelinating neuropathy and the tremor characteristics.

Secondary outcome

- Association between presence of tremor and tremor severity with increase in functional disability and decrease in quality of life in patients with neuropathy, after correction for other impairment modalities such as sensory impairment and muscle weakness.
- Changes in tremor severity, impairment and functioning during follow-up.
- Explorative anaylsis of clinical, laboratory, fMRI and neurophysiological and fMRI characteristics of patients with tremor and patients without tremor to further elucidate the pathophysiology of tremor in demyelinating polyneuropathie.
- The difference in prevalence between patients with demyelinating polyneuropathy and axonal polyneuropathy.

Study description

Background summary

Disabling tremor is an underrecognised symptom of demyelinating and perhaps axonal neuropathy with a yet unknown aetiology. The prevalence of tremor in different types of neuropathy is unclear, as well as tremor characteristics and burden due to tremor in these patients. In addition, there is limited and variable data concerning the effect of treatment of the underlying neuropathy on tremor and of treatment specifically aimed at neuropathic tremor.

Study objective

The main study objective is to determine the prevalence of tremor in patients with neuropathy and describe the tremor characteristics.

Secondary study objectives are:
- To evaluate the functional disability and quality of life in patients with neuropathy with and without tremor.
- To evaluate whether tremor severity correlates with changes in disease activity of underlying neuropathy
- To compare clinical, laboratory, and neurophysiological and fMRI characteristics of patients with neuropathy with tremor with patients without tremor to gain insight in pathophysiology and potential therapies.
- To compare the prevalence of tremor and tremor characteristics in demyelinating polyneuropathy with chronic axonal polyneuropathy.

Study design

Observational cross sectional study additionaly using prospective and retrospective data analysis of patients with polyneuropathy. Presence and characteristics of tremor will be evaluated by means of questionnaires and video assessment, as well as tremor registration, and, in selected patients, reflex loop studies and/or functional MRI in selected patients.

Study burden and risks

There are no risks associated with participation in the study. The major burden is the time associated with the study visits: three visits of 60-90 minutes will take place over a timeperiod of 12-24 months.
A selection of patients (up to twenty patients with and twenty patients without tremor) will be included in an additional part of the study using wristperturbation and functional magnetic resonance imaging (fMRI). In total the additional asessments will maximally cost patients 4 1/4 hours. There will be no hazards for patients participating in these additional assessments if the contra-indications for MRI are applied correctly.

Contacts

Public
Academisch Medisch Centrum

Meibergdreef 9
Amsterdam 1105 AZ
NL
Scientific
Academisch Medisch Centrum

Meibergdreef 9
Amsterdam 1105 AZ
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

Patients with demyelinating neuropathy with and without tremor
1) CIDP
For the diagnosis CIDP we will use the EFNS/PNS criteria for the diagnosis of CIDP. In addition we will include patients fulfilling the clinical criteria and at least two supportive criteria (24).
2) IgM paraproteinemic neuropathy
Patients with chronic distal polyneuropathy with either axonal or demyelinating characteristics and presence of monoclonal IgM antibodies (24).
3) CMT-1A and CMT-1B
Patients with uniform demyelinating polyneuropathy, genetically confirmed in patient or in a first degree relative.

Patients with axonal neuropathy with and without tremor
- EMG confirmed axonal polyneuropathy according to EMG examination in Amsterdam UMC or patients clinically diagnosed with a chronic axonal polyneuropathy during an outpatient clinic visit at the AMC, without an EMG examination. These patients will be included by searching electronic health records in the time frame of January 1st until December 31st 2017;
- the etiology of the neuropathy is either diabetes mellitus, chronic idiopathic axonal polyneuropathy (CIAP) or medication induced (provided the causative drug cannot induce tremor) according to the last diagnosis registered and is not associated with demyelinating disorders;
- neuropathy with a chronic course (symptoms for over 3 months).

Additional inclusion criteria that apply to all groups above:
- age >=18 years
- informed consent

Exclusion criteria

- insufficient knowledge of the Dutch language
- inability to visit the hospital

Study design

Design

Study type:	Observational invasive
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)

Primary purpose: Basic science

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	10-09-2018
Enrollment:	260
Type:	Actual

Ethics review

Approved WMO Date:	22-08-2018
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	12-04-2019
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	21-07-2022
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	02-05-2023
Application type:	Amendment
Review commission:	MEC Academisch Medisch Centrum (Amsterdam) Kamer G4-214 Postbus 22660 1100 DD Amsterdam 020 566 7389 mecamc@amsterdamumc.nl

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
CCMO	NL66092.018.18