Brain networks involved in essential tremor: elucidating tremor pathophysiology using EMG-fMRI

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

Summary

ID

NL-OMON39415

Source
ToetsingOnline

Brief title
ET brain networks

Condition

- Movement disorders (incl parkinsonism)

Synonym
essential tremor, trembling

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Groningen
Source(s) of monetary or material Support: Ministerie van OC&W,Prinses BeatrixFonds (alleen het propranolol deel van de studie)

Intervention

Keyword: EMG-fMRI, essential tremor, homogeneous subgroups, pathophysiology

Outcome measures

Primary outcome

Main outcome measures: changes in patterns of BOLD-signal, coupled to changes in tremor intensity, extent of differentiated muscl use, and kinematic parameters such as reaction time, velocity and acceleration and the presence of 'overshoot'. The different patient groups will be compared to each other and to a healthy control group.

Secondary outcome

NA

Study description

Background summary

The most common motor disorder is pathological tremor. Several years of tremor research have indicated that so-called central oscillators must underlie different forms of pathological tremor. Yet, which brain structures and networks host these oscillators, is still vigorously debated. Essential tremor (ET) is the most common of the tremors characterized by an isolated postural tremor of the upper extremities which can easily be manipulated, making it eminently suitable to investigate tremor related brain areas. By concurrently recording muscle and brain activity, EMG-fMRI is uniquely fitting to couple the overt manifestation of tremor to its generators in the brain.

Study objective

Our primary objective is to identify the brain networks involved in tremor generation in homogeneous groups of ET patients. In addition we will investigate the differences on a behavioral level during goal-directed movements between ET subgroups and healthy controls. In addition, we will investigate the effect of medication on tremor and other kinematic parameters by means of musclereflex measurements (only AMC). We hypothesize that specific

brain networks will be involved in tremor generation in the ET subgroups.

Study design

Observational. Patients with hereditary ET will be selected and divided into groups based on medication response and presence/absence of an intention component in the tremor. In addition healthy age-matched controls will be investigated. Brain activity, muscle activity and movement will be compared during movement tasks that evoke tremor. The whole study will be executed in a multi-center setting (UMCG and AMC).

Study burden and risks

No risks, as long as the exclusion criteria are taken into account. Burden is limited except for patients who are asked to withdraw from medication temporarily. For details: see protocol.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

Healthy subjects:
- subjectively healthy, including vision (after correction)
- 18 years or older and as well as possible age-matched with patients
- informed consent
- righthanded according to the Annett Handedness scale
ET patients:
- ET according to the cirteria defined by the Tremor Investigation Group
- using propranolol or primidone effectively (determined subjectively) and willing to stop this medication temporarily, or intention to start medication use
- heriditary ET
- informed consent
- 18 years or older
- righthanded acoording to the Annett Handedness scale
- subjectively healthy (except for tremor), including vision (after correction)

Exclusion criteria

ET patients:
- absent (Tremor Rating Scale (TRS) Part A 2 UE < 2) or atypical tremor when off medication, as confirmed by polymyography (tremor recording)
- no measurable medication response
- no medication response after wash-in in de novo ET patients
General MR-related:
- presence of metal implants
- presence of electronic implants (eg heart pacemakers) en connections to electronic hardware (eg implanted electrodes)
- claustrophobia
- (possible) pregnancy
General other:
- MMSE < 27
- reumatoid disorder of the wrist, or other non-ET related disorders that can hamper fluent movement of the wrist
- use of medication/drugs that can influence taks performance

Study design

Design

Study type:	Observational non invasive
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Basic science

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	21-11-2011
Enrollment:	130
Type:	Actual

Ethics review

Approved WMO Date:	28-04-2011
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO Date:	12-08-2013
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)

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	NL35788.042.11