# Combined electromyography-functional MRI in patients with tremor for improvement of targeting in stereotactic surgery

Published: 09-10-2007 Last updated: 09-05-2024

We aim to investigate the capability of EMG-fMRI to detect brain areas related to tremor. In addition, we aim to evaluate the role of this technique to define the stereotactical target for tremor suppression.

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

# Summary

### ID

NL-OMON30841

**Source** ToetsingOnline

**Brief title** EMG-fMRI for tremor in stereotactic surgery

# Condition

• Movement disorders (incl parkinsonism)

**Synonym** shaking, trembling, tremor

**Research involving** Human

### **Sponsors and support**

#### Primary sponsor: Academisch Medisch Centrum

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Source(s) of monetary or material Support: Ministerie van OC&W

### Intervention

**Keyword:** electromyography (EMG), functional magnetic resonance imaging (fMRI), stereotactic surgery, tremor

#### **Outcome measures**

#### **Primary outcome**

We will evaluate the predictive value of EMG-fMRI by correlating the overlap of

the area defined by EMG-fMRI with the surgical area, and with clinical outcome

of surgery. Effectiveness of treatment (thalamotomy or DBS) will be assessed

according to the change in the score of specific clinical scales (UPDRS and

TRS).

#### Secondary outcome

not applicable

# **Study description**

#### **Background summary**

On a yearly basis, about 50 patients undergo brain surgery for movement disorders in the AMC, and about 100 patients in The Netherlands. One of the problems encountered during this procedure is the identification of the efficacious target structure. Tremor can have several causes, among which the most common are Essential Tremor (ET) and Parkinson\*s disease (PD). Tremor can also be secondary to brain lesions occurring after head trauma, ischemia or in the context of Multiple Sclerosis. When medical treatment is unsatisfactory, stereotactic surgery (ablative or Deep bran stimulation, DBS) is proposed. Outcome of surgery on tremor is variable: while some patients have satisfying and long-lasting benefit, others have only partial or temporary benefit after surgery. This variability in clinical outcome might be due to differences in the position of the lesion or stimulating electrode or to inter-individual differences in the position of the \*tremor generator\* among patients with different forms of disease. Thus, there is a need to better define the surgical target for different kinds of tremor and even to tailor the target area for each individual patient.

Functional MRI (fMRI) combined with electromyography (EMG) is a new technique that, compared to usual fMRI protocols, allows correlation of involuntary movements to brain activity. In this study, we will use EMG-fMRI technique to study tremor in patients suitable for stereotactic surgery. We hypothesize that, in patients in whom surgery effectively suppresses tremor, the area defined by EMG-fMRI overlaps with the surgical area.

#### **Study objective**

We aim to investigate the capability of EMG-fMRI to detect brain areas related to tremor. In addition, we aim to evaluate the role of this technique to define the stereotactical target for tremor suppression.

#### Study design

This is a pilot, prospective, cohort study. Patients will undergo one simultaneous EMG-fMRI recording and neurological evaluation by means of specific clinical scales

#### Study burden and risks

Patients will undergo one site visit, during which standardized clinical evaluations will be performed with the aid of clinical scales and videos. During the same visit, patient will undergo an fMRI scan and simultaneous recording of movements, with the help of surface EMG electrodes. Patient data is blinded. We will then analyse the correlation of tremor and brain activity, to define tremor related areas within the thalamus and basal ganglia. Patients participating in part B will undergo an additional standardized clinical evaluation during their normally scheduled post-operative follow-up evaluation. The proposed investigation bears virtually no risks and is usually well tolerated. EMG-fMRI can potentially improve target-identification for DBS, thus improving surgical outcome. Ultimately, this study could provide a new tool to predict the best surgical target for each individual patient and improve the benefit of stereotactic neurosurgery for tremor.

# 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**

Previous thalamotomy for the treatment of tremor or inclusion in the waiting list for DBS;Presence of tremor in at least one arm ;Age above 18 years

### **Exclusion criteria**

MR-incompatible implanted metal bodies, including stereotactic implant for Deep Brain Stimulation.;Other contraindications for MR (Claustrophobia, obesity, etc.);Previous brain surgery other than thalamotomy ;Use of medicines/drugs that could influence the performance during the tasks (such as anti-epileptic drugs, neurodepressants, etc.);Pregnancy or suspected pregnancy;Incapability to give informed consent

# Study design

# Design

Study type: Observational invasive		
Masking:	Open (masking not used)	
Control:	Uncontrolled	
Primary purpose:	Diagnostic	

### Recruitment

NL	
Recruitment status:	Pending
Start date (anticipated):	01-11-2007
Enrollment:	40
Туре:	Anticipated

# **Ethics review**

Approved WMO	
Application type:	First submission
Review commission:	METC Amsterdam UMC

# **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 CCMO **ID** NL19347.018.07