

Movement Diagnostic System: Quantitative diagnosis of patients with Parkinson's Disease, essential tremor and dystonia, a closed-loop approach with fMRI

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Our goal is to develop and validate a Movement Diagnostic System (MDS) to accurately locate specific CNS pathological changes in ET, PD-T and DYS, with the use of fMRI and scanner compatible EMG, accelerometry, video, and wrist perturbator.

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

Summary

ID

NL-OMON36806

Source

ToetsingOnline

Brief title

Movement Diagnostic System

Condition

- Movement disorders (incl parkinsonism)

Synonym

involuntary movements, movement disorders

Research involving

Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum

Source(s) of monetary or material Support: STW financieert het project. Het budget van STW is afkomstig van NWO en van het ministerie van economische zaken.,CenS (Micro) Electronics BV, Apeldoorn, NL,Moog-FCS-BV, MOOG Inc., Nieuw-Vennep, NL,Noldus, Wageningen, NL ,TMSi, Oldenzaal, NL

Intervention

Keyword: closed-loop approach, diagnosis, fMRI, movement disorders

Outcome measures

Primary outcome

Differentiation between ET, PD-T and DYS based on brain activations specifically related to involuntary movements. With external measures and perturbation of the closed sensorimotor loop during fMRI we expect to find involvement of the olivocerebellar networks in ET, the striatum in PD-T and a widespread involvement of basal ganglia, thalamus, and cerebral cortex in dystonia.

Secondary outcome

Observation and identification of the brain regions involved in (the early stages) of movement disorders with overlapping symptoms will contribute to the knowledge on the occurrences and causes of these diseases on a more fundamental level.

Study description

Background summary

Essential tremor (ET), Parkinsonian tremor (PD-T) and limb dystonia (DYS) are ubiquitous and disabling. Diagnostic tools are limited, especially in early

disease stages leading to a delay in targeted therapy. ET, PD-T and DYS are diseases of the central nervous system (CNS), with different pathological changes. Functional MRI (fMRI) combined with measures of movement including electromyography (EMG) allows to relate voluntary and involuntary movements directly to brain activity providing a promising diagnostic in movement disorders. Combination with a wrist manipulator, influencing motor and sensory inputs and outputs potentially allows *closed-loop system identification* and may further improve movement disorders diagnostics.

Study objective

Our goal is to develop and validate a Movement Diagnostic System (MDS) to accurately locate specific CNS pathological changes in ET, PD-T and DYS, with the use of fMRI and scanner compatible EMG, accelerometry, video, and wrist perturbator.

Study design

This is a pilot prospective cohort study. The study consists of Part A, outside the scanner, including a standardized neurological assessment with standardized rating scales and a measurement with wrist manipulator, EMG, accelerometry and electroencephalogram (EEG) followed by Part B the main experiment inside the scanner, including the MR-compatible devices with fMRI as a diagnostic tool . Before this visit, a first visit is scheduled during which the eligibility of the participants will be evaluated.

Study burden and risks

Participants will undergo one or two site visits. The first visit will take about 1 hour during which the eligibility of the participants will be evaluated by performing standardized clinical evaluations with the aid of inclusion questionnaire and a short neurological examination. Preferably, this visit is planned after a regular hospital visit. Patients are requested to slowly reduce medication that suppresses the hyperkinetic symptoms prior to the second visit. During this visit, two consecutive experimental set-ups will be performed. In part A of the protocol, after clinical evaluation, participants will perform motor tasks while perturbation torques are applied to the subject*s wrist by a wrist manipulator. Recordings are made with surface EMG electrodes, kinematic sensors, and EEG electrodes. This will take up to 1* hours including preparation. After an hour break we will continue with part B. In this stage, the severity of the symptoms is known and the perturbation protocol is tailored to the specific participants. Participants will perform motor tasks and perturbation torques are applied during fMRI measurement. Motor responses are measured with the same EMG electrodes and kinematic sensors as in part A. Participants will be in the scanner for one hour. The second visit will take approximately 3.5 hours in total, including one hour break. The proposed

investigation bears virtually no risks and is expected to be well-tolerated. All safety requirements regarding the instruments used in this study will be met in accordance with *instrumenteel bedrijf* and the clinical physicists responsible for the MRI. The developed system potentially improves diagnosis of movement disorders, thus shortening the diagnostic procedure and improving the treatment effectiveness. There is no direct benefit from this study for the participants.

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

- 18 years or older
- Right-handed according to the Edinburgh Handedness Inventory
- Willingness to stop medication intake for eight hours prior to investigations

And either:

- Essential tremor according to criteria defined by the Tremor Investigation Group, moderate to severe tremor (Tremor Rating Scale Part A 2 UE>2) ;
- Hereditary ET (positive family history: at least one affected relative in immediate family; Onset in patient and family member before age 65);
- Positive effect of propranolol on tremor.
- Parkinson*s disease according to the UK Brain Bank criteria for Parkinson*s disease;
- No major fluctuations in symptoms due to medication;
- No severe dyskinesia.
- Limb dystonia with at least 35 points on the motoric part of the Burke-Fahn-Marsden Dystonia Rating Scale
- Healthy age and sex-matched controls

Exclusion criteria

- MR-incompatible implanted metal bodies, including stereotactic implant for Deep Brain Stimulation and pacemakers.
- Other contraindications for MR (Claustrophobia, obesity, etc.)
- 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
- Other neurological disorder than ET/PD-T/dystonia including dementia
- Abnormalities of the hand/wrist or prior surgery of the hand/wrist

Study design

Design

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

Recruitment

NL	
Recruitment status:	Recruiting

Start date (anticipated):	13-12-2011
Enrollment:	100
Type:	Actual

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	ID
Other	9427 (trialregister)
CCMO	NL35362.018.11