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

No registrations found.

Ethical review	Not applicable
Status	Pending
Health condition type	-
Study type	Observational non invasive

Summary

ID

NL-OMON28203

Source
NTR

Brief title
Movement Diagnostic System

Health condition

movement disorders
diagnosis
closed-loop approach
fMRI

Sponsors and support

Primary sponsor: Academic Medical Center
University of Amsterdam
PO-box: 22660
1100 DD Amsterdam
Tel: +31 (0)20.5669111
Source(s) of monetary or material Support: This project has financial support of the

NWO technology foundation STW (NeuroSIPE 10739, www.neurosipe.nl)

Intervention

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 olivocerbellar 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

Rationale:

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 perturbator, influencing motor and sensory inputs and outputs allows ‘closed-loop system identification’ and may further improve movement disorders diagnostics.

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 perturbator, 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 population:

Patient groups with ET, PD-T and DYS of twenty-five patients each, and twenty-five healthy subjects will be included. To test the feasibility and to optimize the measurement protocol we will first include five participants of each group, after which we will add 20 more participants to each of the four groups.

Main study parameters/endpoints:

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 olivocerbellar networks in ET, the striatum in PD-T and a widespread involvement of basal ganglia, thalamus, and cerebral cortex in dystonia.

Nature and extent of the burden and risks associated with participation, benefit and group relatedness:

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 an 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 perturbator. Recordings are made with surface EMG electrodes, kinematic sensors, and EEG electrodes. This will take up to 1½ 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.

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Study design

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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 1½ hours including preparation. After an hour break we will continue with part B, where the entire experimental setup will be applied, including fMRI.

Intervention

N/A

Contacts

Public
Academic Medical Center, University of Amsterdam
S. Sharifi
Amsterdam
The Netherlands
+31 (0)20 5663614
Scientific
Academic Medical Center, University of Amsterdam
S. Sharifi
Amsterdam
The Netherlands
+31 (0)20 5663614

Eligibility criteria

Inclusion criteria

1. 18 years or older;

2. Right-handed according to the Edinburgh Handedness Inventory;

3. Willingness to stop medication intake for eight hours prior to investigations.

And either:

1. Essential tremor according to criteria defined by the Tremor Investigation Group, moderate to severe tremor (Tremor Rating Scale Part A 2 UE>2);

2. Hereditary ET (positive family history: at least one affected relative in immediate family; Onset in patient and family member before age 65);

3. Positive effect of propranolol on tremor;

4. Parkinson’s disease according to the UK Brain Bank criteria for Parkinson’s disease;

5. No major fluctuations in symptoms due to medication;

6. No severe dyskinesia;

7. Limb dystonia with at least 35 points on the motoric part of the Burke-Fahn-Marsden Dystonia Rating Scale;

8. Healthy age and sex-matched controls.

Exclusion criteria

1. MR-incompatible implanted metal bodies, including stereotactic implant for Deep Brain Stimulation and pacemakers;

2. Other contraindications for MR (Claustrophobia, obesity, etc.);

3. Use of medicines/drugs that could influence the performance during the tasks (such as anti-epileptic drugs, neurodepressants, etc.);

4. Pregnancy or suspected pregnancy;

5. Incapability to give informed consent;

6. Other neurological disorder than ET/PD-T/dystonia including dementia;

7. Abnormalities of the hand/wrist or prior surgery of the hand/wrist.

Study design

Design

Study type:	Observational non invasive
Intervention model:	Parallel
Allocation:	Non controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-06-2011
Enrollment:	100
Type:	Anticipated

Ethics review

Not applicable

Application type:	Not applicable

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
NTR-new	NL2755
NTR-old	NTR2894
Other	:
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Study results

Summary results
N/A