Next Move in Movement Disorders

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Ethical review	Approved WMO
Status	Recruiting
Health condition type	Neurological disorders congenital
Study type	Observational invasive

Summary

ID

NL-OMON52964

Source
ToetsingOnline

Brief title
NEMO

Condition

- Neurological disorders congenital
- Movement disorders (incl parkinsonism)

Synonym
Hyperkinetic movement disorders, involuntary movements

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Groningen
Source(s) of monetary or material Support: ZonMW TOP subsidie,Europese Unie;Provincie Fryslân;Janivo Stichting;Mandema stipendium,ZiuZ Medical B.V.

Intervention

Keyword: Artificial intelligence, Computer-aided diagnosis tool (CAD), Hyperkinetic movement disorders, Machine learning

Outcome measures

Primary outcome

During a single hospital visit or at an external location, participants will be questioned about clinical parameters, such as age at onset, will fill out several questionnaires on non-motor symptom severity, and will be asked to perform several simple motor tasks with the arms. While executing these tasks, participants will be recorded using 3D video, motion sensors, and muscle activity sensors. Expert-based phenotype classification by three experts, based on the video recordings and clinical parameters, will serve as input for machine learning. Phenotype specific data clusters of the clinical parameters, 3D video, motion sensors, muscle activity sensors, FDG-PET imaging, fMRI, and machine learning will be used to develop CAD models able to differentiate the movement disorders. Algorithms, data quality assessment, discriminant feature design, classifier training and validation will be applied using these data clusters in machine learning.

Secondary outcome

Furthermore, the discrepancies between the phenotyping of the CAD-tool and the clinical experts will be analyzed to improve the CAD-tool and gain further understanding about clinical judgement.

Moreover, the pathophysiological brain process of dystonia, tremor, and myoclonus will be analyzed by linking phenotypes to patterns of regional

changes in brain function.

Additionally, it will be analyzed whether regional change patterns in brain

function are phenotype- of genotype-specific in myoclonus-dystonia.

Study description

Background summary

Hyperkinetic movement disorders are defined as excessive involuntary movements, including dystonia, myoclonus and tremor. Each single type of movement disorder has its own clinical presentation, but frequently complex and variable mixed forms occur. As a result, only highly specialized experts can classify movement disorders correctly. However, even these experts are often not in agreement about the diagnosis, leaving numerous patients without good clinical description (phenotype). Incorrect phenotyping is a major problem which precludes good diagnosis in patients, evaluating the natural course, delivering tailored treatment, and evaluating treatment effects in hyperkinetic movement disorders.

Study objective

The primary objective is the development of a computer-aided diagnosis tool (CAD-tool) that enables specialists to improve the diagnosis, treatment, and evaluation of hyperkinetic movement disorders.
The secondary objectives is are:
1) To analyze discrepancies between expert-based phenotype classification and CAD-tool outcomes, to improve the CAD-tool and our knowledge of clinical judgment.
2) To enable further optimization of the classification of the dystonia, tremor, myoclonus, and mixed phenotypes by adding imaging patterns to the machine learning.
3) To gain insight in pathophysiological brain processes of dystonia, tremor, and myoclonus phenotypes by linking phenotypes to regional change patterns in brain function.
4) To study whether regional change patterns in brain function are phenotype- or genotype-specific in myoclonus-dystonia.

Study design

The study design is a cross-sectional translational study which aims to develop a CAD-tool for hyperkinetic movement disorders. The study consists of a pilot, and two three study parts: A, and B, and C. During the pilot the most

discriminating tasks will be selected for further use in part A and B. In part A and B different groups of patients will be included. Part C consists of the FDG-PET and MRI imaging.

Study burden and risks

The risk of the study parts A and B is considered minimal because no invasive apparatuses are used and the tasks that are included in the study are not burdensome. Subjects are not expected to experience direct clinical benefit from participation in the study. However, in the future, this CAD-tool will help provide fast and correct diagnosis for new patients. Additionally, the CAD-tool can be used for evaluation of treatment, which could be beneficial for the participants. The risk associated with participation in part C is considered negligible and the burden can be considered acceptable since there is great experience with the scans in normal diagnostic work up of patients with movement disorders and significant side effects are not known.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adolescents (12-15 years)
Adolescents (16-17 years)
Adults (18-64 years)
Children (2-11 years)

Inclusion criteria

- >= 16 years of age.
- Patients with a clinically confirmed diagnosis of one of the included single phenotypes (dystonia, tremor, myoclonus, tics, chorea, spasticity, ataxia) OR mixed phenotyping OR healthy controls.
- For pediatric patients in part A and part B >= 6 years of age

Exclusion criteria

- Other neurological conditions that lead to movement problems other than hyperkinetic movement disorders.
- Other conditions that lead to impaired hand or arm function.
- With regard to healthy subjects: no first degree family member of a patient with a hyperkinetic movement disorder.
- Silver allergy
- Pace-makers
- For pediatric patients: not able to follow instructions

Study design

Design

Study type: Observational invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	22-02-2019

Enrollment:	534
Type:	Actual

Ethics review

Approved WMO Date:	18-02-2019
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO Date:	20-06-2019
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO Date:	28-04-2020
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO Date:	20-07-2020
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO Date:	13-12-2021
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO Date:	29-08-2022
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	NL67013.042.18