DiPAR: Diagnosing Parkinson*s Disease by neuromuscular function evaluation

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To assess in a pilot setting whether there are differences (including sensitivity and specificity) in pen motion, grip force patterns and muscle activity, derived using a newly developed system for handwriting monitoring, between A: patients with...

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

Summary

ID

NL-OMON38380

Source
ToetsingOnline

Brief title
DiPAR

Condition

- Movement disorders (incl parkinsonism)

Synonym
movement disorders, Parkinson's disease

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Groningen
Source(s) of monetary or material Support: Europese Unie (FP7-R4SME)

Intervention

Keyword: diagnostic medicine, electromyography (EMG), finger force recordings, Parkinson's disease

Outcome measures

Primary outcome

Pen tip motion, velocity and acceleration and pen grip forces (in the time and

frequency domain) during each of the tasks, compared between groups. In

addition mean EMG, EMG variability and EMG power peaks will be assessed.

Secondary outcome

NA

Study description

Background summary

Earlier studies suggest that assessing the frequency and timing of force modulation allows to quantify differences between healthy subjects and PD patients who do not yet present the typical PD features, such as rest tremor, limb stiffness and inability to perform voluntary movement. In the present study, a newly developed system for handwriting monitoring that incorporates finger grip force recordings is evaluated for its abilities to differentiate between Parkinson*s disease and other movement disorders that show partially similar symptoms (essential tremor, enhanced physiological tremor, psychogenic tremor, dystonia and spasticity).

Study objective

To assess in a pilot setting whether there are differences (including sensitivity and specificity) in pen motion, grip force patterns and muscle activity, derived using a newly developed system for handwriting monitoring, between A: patients with essential tremor, psychogenic tremor or enhanced physiological tremor and B: patients with dystonia (writer*s cramp and torticollis spasmodica), spasticity or Parkinson*s disease. Within study B, the effect of Parkinsonian medication on the above measures will also be assessed. Finally, to further assess future clinical value of the handwriting system, the reproducibility of the above measures except muscle activity, will be

determined in healthy subjects (study C).

Study design

Observational study. Subjects have to execute line drawing, spiral and circle drawing and text writing on a writing tablet while holding a pen that can measure grip force. Arm joint kinematics will be determined using small cameras. In addition EMG will be collected from lower- and upper arm muscles.

Study burden and risks

There are no risks or benefits, but a potential burden is associated with the overnight (12 hour) withdrawal of anti-Parkinsonian medication in Parkinson patients and the wash-out of medication in essential tremor patients (if applicable). The burden is small however and if symptoms are increased due to withdrawal/wash-out of medication, they will disappear soon after medication is taken as usual. The withdrawal is justified because it allows to assess the patients while they are not under the influence of their medication, which is essential for this type of study.

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

All subjects
- right*handed
- informed consent
- ability to hold a pen for at least half an hour
PD patients
- diagnosis according to the UK Parkinson*s Disease Society Brain Bank clinical diagnostic criteria
- symptoms scored as Hoehn & Yahr I*III
- age: >50 years
Essential tremor
- diagnosis according to the criteria defined by the Tremor Investigation Group for more than 5 years
Enhanced physiological tremor
- diagnosis based on polymyography
Psychogenic tremor
- diagnosis based on polymyography
Dystonia (writer*s cramp or torticollis spasmodica)
- clinical diagnosis of dystonia
- last botulinum toxin treatment at least 2 months prior to study investigation
Post*stroke spasticity
- clinical diagnosis of post*stroke spasticity (afflicting at least right hand function)

Exclusion criteria

All subjects
- (other) neurological or motor disorder (than that included for)
- Mini Mental State Examination (MMSE) score <26
- Use of medication influencing movement other than for Parkinson's disease or essential tremor
PD patients
- Not willing to comply with overnight-withdrawal of Parkinson-related medication
- Tremor-dominant PD
ET patients
- Not willing to comply with medication withdrawal, starting 7 days prior to study investigation

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:	Diagnostic

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	22-02-2012
Enrollment:	90
Type:	Actual

Ethics review

Approved WMO Date:	22-03-2011
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO Date:	16-11-2012
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	NL35538.042.11