Behavioural and physiological measures of the effects of dopamine on attention in Parkinson*s disease

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

Summary

ID

NL-OMON34140

Source
ToetsingOnline

Brief title
PD and the role of dopamine in attention

Condition

- Movement disorders (incl parkinsonism)

Synonym
Parkinson's disease, PD

Research involving
Human

Sponsors and support

Primary sponsor: Vrije Universiteit
Source(s) of monetary or material Support: NWO

Intervention

Keyword: Attention, Dopamine, Learning, Parkinson's disease

Outcome measures

Primary outcome

Outcome parameters are: behavioural measures of response latency and accuracy

and non-invasive electrophysiological measures in the form of event-related

potentials.

Secondary outcome

none

Study description

Background summary

The mesolimbic dopamine system has a broad impact on brain function and plays a role in various aspects of emotional and cognitive processing. Parkinson*s Disease (PD) causes abnormalities in this system that lead to emotional, behavioural and cognitive symptoms, including changes in the attentional processing of sensory input.

Study objective

This project is motivated by neuroscientific theory regarding the role of the mesolimbic dopamine system in selective attention. It aims to elucidate how the dopamine system affects attention and to determine the role abnormal functioning of this system plays in creating cognitive and emotional symptoms of PD. The study will accordingly increase our understanding of non-motor deficits in PD and the role of dopamine replacement therapy therein.
Our hypothesis is that dopamine deficit caused by PD will have a strong negative impact on attention and the assignment of priority to sensory stimuli. In particular, sensitivity of attention to the novelty of stimuli and to their reward value will be reduced. These symptoms will be alleviated when dopamine availability is increased through dopamine replacement medication.

Study design

Cross-sectional pre-post intervention design using behavioural measures of response time and accuracy and electroencephalographic measures of brain activity (EEG) during execution of cognitive tasks.

Intervention

Levodopa administration after overnight withdrawal.

Study burden and risks

Participants visit the Transitorium building of the VU on one occasion and are tested within their home on two separate days.

Day 1: Completion of a battery of pen-and-paper neuropsychological assessment inventories; explanation of and acquaintance with EEG apparatus. VU Transitorium building, 2 hours.

Day 2: First test session at the home of the participant. One half hour setting up EEG recording; 1.5 hours experimental tasks. For one half of patients, tests are done under conditions of overnight withdrawal from levodopa. For the other half, overnight withdrawal occurs on day 3.

Day 3: Second test session; as per day 2.
None of the treatments and measurements causes any significant risk to health or well-being of the patients or controls.

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

Diagnosis of idiopathic PD following UK Brain Bank criteria in Hoehn and Yahr stages2-3
40-75 years old
informed consent
On DA replacement therapy

Exclusion criteria

psychotropic medication other than DA therapy (at least 4 weeks off medication)
major somatic disorder or known psychiatric diagnosis
Dementia (MMSE <23)

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)

Primary purpose: Basic science

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	28-02-2011
Enrollment:	72
Type:	Actual

Ethics review

Approved WMO

Date:	27-10-2010
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
CCMO	NL32718.029.10