Reward mechanisms, mood and motivational symptoms in Parkinson's disease: an experimental approach

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

Summary

ID

NL-OMON31022

Source
ToetsingOnline

Brief title
Mood and motivation in PD.

Condition

- Movement disorders (incl parkinsonism)

Synonym
emotional blunting, lack of initiative

Research involving
Human

Sponsors and support

Primary sponsor: Universiteit Maastricht
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: methylphenidate, motivation, Parkinson's disease, pramipexole

Outcome measures

Primary outcome

Main study parameters are the performance on neuropsychiatric and neuropsychological tests for both groups, including assessments of cognitive status, mood, apathy, and an observation of spontaneous self-reward behaviour. These outcome measures will be rated on three different testing days, before and after the administration of methylphenidate, pramipexole or placebo.

Secondary outcome

not applicable

Study description

Background summary

In Parkinson's disease (PD) degeneration of dopaminergic cells in the mesocorticolimbic pathway is implied int he pathophysiology of several non-motor symptoms related to motivation and reward, such as apathy, depression, and hedonistic homeostatic dysregulation (HDD), a syndrome that is characterized by obsessive behaviour, addiction, compusive seeking of dopamine replacement therapy (DRT), and hypersexuality. Apathy is reproted in 16 to 42 % of PD patients, while depression occurs in in 25 to 40 %. Both apathy and depression have a serious negative impact on everyday functioning, cognitive and motor performance and quality of life for both patient and partner or caretaker. HDD, although less prevalent (around 4% of patients), can also be severely disruptive. Insight in the pathophysiology of these syndromes may pave the way for rational treatments and improved outcomes.

Study objective

The objective of this project is to study the role of dopaminergic mechanisms in apathy, mood and HDD in patients with PD. What is the involvement of the dopaminergic neurotransmitter system in motivation and reward processes in PD

and the clinical correlates of dysfunction of reward systems in an experimental approach?

Study design

A randomized double-blind placebo-controlled, crossover design with three arms.

Intervention

All subjects receive a 10 mg methylphenidate challenge, a 500 µg pramipexole challenge and a placebo condition.

Study burden and risks

The burden and risks associated with the present study are related to three visits on three separate days. Each day will start with the administration of a neuropsychiatric and neuropsychological investigation (2,5 hours), observation of spontaneous behaviour (15 minutes), accordingly the methylphenidate, pramipexole challenge or placebo, and after 1.5 hours the outcome measures are repeated (1,5 hours). Methylphenidate is used in previous studies in patients with PD without reporting only some mild adverse events and pramipexole is a common prescribed medication in PD patients, so burden en risks are expected to be minimal. Because the main objective is to study the role of dopaminergic mechanisms in apathy, mood and HDD in patients with PD, the inclusion of PD patients in the present study is necessary.

Contacts

Public
Universiteit Maastricht

Dr.Tanslaan 12
6229 ET
NL
Scientific
Universiteit Maastricht

Dr.Tanslaan 12
6229 ET
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

-Idopathic Parkinson's disease
-Informed consent

Exclusion criteria

-Other concurrent neurological diseases than PD
-Concurrent psychiatric disease
-Use of psychopharmacological medication
-Abuse of alcohol and drugs
-Cognitive deterioration as operationalized by a score of <23 on the MMSE
-Use of levodopa preparations of dopamine agonists.

Study design

Design

Study type:	Interventional
Intervention model:	Crossover
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Placebo
Primary purpose:	Basic science

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	06-05-2008
Enrollment:	50
Type:	Actual

Medical products/devices used

Product type:	Medicine
Brand name:	Ritalin
Generic name:	Methylphenidate
Registration:	Yes - NL outside intended use
Product type:	Medicine
Brand name:	Sifrol
Generic name:	Pramipexole
Registration:	Yes - NL intended use

Ethics review

Approved WMO Date:	16-10-2007
Application type:	First submission
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO Date:	20-12-2007
Application type:	First submission
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)

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
EudraCT	EUCTR2007-004810-14-NL
CCMO	NL19462.068.07