Varenicline, a partial nicotinic receptor agonist, for the treatment of excessive daytime sleepiness in Parkinson*s disease: a placebo-controlled cross-over study

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This study is aimed to determine the efficacy of varenicline in reducing EDS in PD patients.

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

Summary

ID

NL-OMON43609

Source
ToetsingOnline

Brief title
Vareniciline for excessive daytime sleepiness in Parkinson*s disease

Condition

- Movement disorders (incl parkinsonism)

Synonym
idiopathic Parkinson's disease, Parkinson's disease

Research involving
Human

Sponsors and support

Primary sponsor: Vrije Universiteit Medisch Centrum

Source(s) of monetary or material Support: Ministerie van OC&W,Centre for Human Drug Research,CHDR;Pfizer BV;parkinson vereniging,Pfizer

Intervention

Keyword: Excessive daytime sleepiness, Nicotinic receptor agonist, Parkinson's disease, Varenicline

Outcome measures

Primary outcome

The primary clinical outcome measure is the difference on Epworth Sleepiness Scale (ESS) between the two treatments (varenicline versus placebo).

Secondary outcome

The secondary outcome measures are the differences on the SCOPA-sleep, Pittsburgh Sleep Quality Index, the Abnormal Involuntary Movements Scale, the Fatigue Severity Scale and the Medical Outcome Survey Short Form (SF-36) for quality of life. A neurophysiological outcome measure is the mean time before falling asleep in the Maintenance of Wakefulness Test (MWT). In a randomized subgroup the differences in pharmacodynamic effects on central nervous system functioning of varenicline after first administration and in steady state condition through scores on the NeuroCart test battery are investigated.

Study description

Background summary

Sleep disturbances are common in Parkinson*s disease (PD) and include excessive daytime sleepiness (EDS) that has been reported in up to 50% of patients. Relatively little therapeutic research has addressed the problem of EDS and current treatment is largely aimed at reducing the dose of dopaminergic

medication while trying to maintain sufficient motor control which unfortunately often fails. Apart from degeneration of dopaminergic neurons, a decrease in cholinergic projections to the brain arousal areas may be at least partly responsible for the occurrence of EDS in PD. Smoking in narcoleptic patients diminishes sleep attacks and EDS , thus one may hypothesize that nicotinergic stimulation of the brain arousal areas may improve EDS in PD. Therefore the effect of varenicline, an alpha4beta2 nicotinic receptor partial agonist (nAChR), on EDS in PD will be studied in a placebo-controlled cross-over study.

Study objective

This study is aimed to determine the efficacy of varenicline in reducing EDS in PD patients.

Study design

The study is a randomized, double blind, placebo-controlled clinical trial with a within-subject crossover design.

Intervention

Patients will be randomly assigned to start an active treatment or placebo and complete two periods of four weeks with a washout period of two weeks.

Study burden and risks

Patient characteristics will be obtained among several scales on sleep, mental state and quality of life. The patients will undergo a polysomnography and a safety evaluation including ECG and renal function. MWT and plasma levels are measured in the challenge fase and steady state condition after four weeks of treatment. After a two week washout period all procedures are repeated for the cross-over study. Adverse events may include nausea, headache, insomnia and abnormal dreams and will be carefully monitored.

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

-idiopathic Parkinson's Disease (PD) according to criteria UK PD Society Brain Bank
-receiving stable PD medications for at least 4 weeks before and throughout the study
-excessive daytime sleepiness (defined by a score of >10 on the Epworth Sleeping Scale)

Exclusion criteria

- patients receiving medications with known central depressant effects
- dementia
- depression
- known sleep apnea or narcolepsy
- current smoking
- contra-indications for treatment with varenicline (psychiatric illness, renal failure, ischemic cardial disease, stroke, insuline-dependent diabetes)

Study design

Design

Study phase:	3
Study type:	Interventional
Intervention model:	Crossover
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Active
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	10-05-2013
Enrollment:	46
Type:	Actual

Medical products/devices used

Product type:	Medicine
Brand name:	champix
Generic name:	varenicline
Registration:	Yes - NL outside intended use

Ethics review

Approved WMO Date:	25-07-2012
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	09-08-2012
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	06-06-2013

Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	29-04-2015
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	27-05-2015
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	02-08-2016
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	16-08-2016
Application type:	Amendment
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
EudraCT	EUCTR2012-001530-34-NL
CCMO	NL40128.029.12