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A randomized double blind placebo controlled study to evaluate the modulation of cognitive functions in Parkinson's subjects by sildenafil

Submission date 30/08/2005	**Recruitment status** No longer recruiting	[ ] Prospectively registered [ ] Protocol [ ] Statistical analysis plan [ ] Results [ ] Individual participant data [ ] Record updated in last year
Registration date 26/09/2005	**Overall study status** Completed	
Last Edited 23/05/2016	**Condition category** Nervous System Diseases	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

A1481189

Study information

Scientific Title
A randomized double blind placebo controlled study to evaluate the modulation of cognitive functions in Parkinson's subjects by sildenafil

Acronym
SCOPE

Study objectives
That 48 weeks of sildenafil therapy will stabilize or slow down the progression of cognitive impairment in Parkinson's disease subjects with mild cognitive impairment when compared with untreated Parkinson's disease controls. The study will also assess the effects of sildenafil upon motor state and olfaction in Parkinson's disease since these parameters may also be improved by sildenafil.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not provided at time of registration

Study design
Randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Not specified

Study type(s)
Treatment

Participant information sheet

Health condition(s) or problem(s) studied
Parkinson's disease (PD)

Interventions
Sildenafil dosing in the treatment group will start at 50 mg once daily for 4 weeks. Dosing is then increased to 100 mg daily for a further 44 weeks. The control group will receive matching placebo teatment for 48 weeks.

Intervention Type

Drug

Phase
Not Specified

Drug/device/biological/vaccine name(s)
Sildenafil

Primary outcome measure
1. To test if 48 weeks of sildenafil therapy will result in improved cognitive functions in Parkinson's disease subjects as measured by the paired association learning (PAL) test
2. To test if 48 weeks of sildenafil therapy will result in improved olfaction in Parkinson's disease subjects as measured by the UPSIT test

Secondary outcome measures
To test if 48 weeks of sildenafil therapy will result in improved motor and cognitive function in Parkinson's disease subjects as measured by the Unified Parkinson's Disease Rating Scale (UPDRS), Dyskinesia Rating Scale, Spatial Working Memory Test and Reaction Time Test.

Overall study start date
14/12/2004

Completion date
30/09/2006

Eligibility

Key inclusion criteria
1. Male or female subjects (excluding women of child bearing potential) between the ages of 50 and 80 years, inclusive
2. Diagnosis of Parkinson's disease according to UK Parkinson's Disease Society Brain Bank Criteria
3. Diagnosis of Parkinson's disease >12 months
4. Mild cognitive impairment insufficient to fulfill Diagnostic and Statistical Manual of Mental Disorders, Fourth Edition (DSM-IV) criteria for dementia, with MMSE score 18-27
5. University of Pennsylvania Smell Identification Test (UPSIT) test score of <30
6. Subjects must be willing and able to provide written informed consent

Participant type(s)
Patient

Age group
Adult

Lower age limit
50 Years

Upper age limit
80 Years

Sex
Both

Target number of participants
100 subjects, 50 randomised to both sildenafil and placebo group

Key exclusion criteria
1. Subjects with evidence of severe or unstable concomitant medical illness
2. Known hypersensitivity to, or current use of sildenafil, or other PDE5 inhibitors
3. Clinically significant orthostatic hypotension (defined as disabling postural light-headedness or syncopal episodes associated with a fall in systolic blood pressure on standing of over 30 mmHg)
4. Patient taking anti-psychotic or cholinesterase inhibitor medication
5. Patient taking dopamine agonists
6. Major depressive disorder
7. Anosmia secondary to head injury/non-PD related cause
8. Exclusion of patients with Multiple Systems Atrophy
9. Exclusion of patients with colour-blindness
10. Subjects who were prescribed and/or are taking nitrates or nitric oxide donors in any form (oral, sub-lingual, tansdermal, inhalation,aerosols), alpha blockers and/or class IA or III anti-arrhythmic medication
11. Use of medication known or suspected to be potent or moderate inhibitors of cytochrome P4503A4 (excluding ketoconazole, itraconazole, cimetidine, ritonavir)
12. Subjects with congenital QT prolongation
13. Electrocardiogram (ECG) evidence of severe life-threatening rhythm or ischaemic disturbances including acute myocardial infarction (within last year), left bundle branch block, or ventricular tachycardia
14. QTcF prolongation >500 msecs
15. Sustained hypertension >170 mmHg systolic or >110 mmHg diastolic; sustained hypotension <90 mmHg systolic or <50 mmHg diastolic
16. History of regular alcohol abuse within 6 months of screening
17. Treatment with investigational drug within 30 days or 5 half-lives (whichever is longer) preceding the first dose of study medication

Date of first enrolment
14/12/2004

Date of final enrolment
30/09/2006

Locations

Countries of recruitment
England

United Kingdom

Study participating centre

Regional Neurosciences Centre
Newcastle
United Kingdom
NE46BE

Sponsor information

Organisation
Pfizer Inc. (USA)

Sponsor details
Groton Laboratories
Clinical Sciences Dept.
445 Eastern Point Road
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CT06340

Sponsor type
Industry

ROR
https://ror.org/01xdqrp08

Funder(s)

Funder type
Industry

Funder Name
Study is fully funded by Pfizer Inc. (USA)

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration