

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

<b>Submission date</b> 30/08/2005	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered
<b>Registration date</b> 26/09/2005	<b>Overall study status</b> Completed	<input type="checkbox"/> Protocol
<b>Last Edited</b> 23/05/2016	<b>Condition category</b> Nervous System Diseases	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> Record updated in last year

**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 treatment 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, transdermal, 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 msec
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  
Groton  
United States of America  
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