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A large randomised long-term assessment of the relative effectiveness of surgery for Parkinson's Disease (PD)

Submission date	Recruitment status	[X] Prospectively registered
02/05/2001	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
02/05/2001	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
11/06/2010	Nervous System Diseases	

Plain English summary of protocol
Not provided at time of registration

Study website
http://www.pdsurg.bham.ac.uk/

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
G9900797

Study information

Scientific Title

Acronym
PD SURG

Study objectives
PD SURG will evaluate whether STN surgery has a cost-effective role in the treatment of PD and will also investigate the optimal timing of such surgery. The trial will compare surgery with active medical therapy (with surgery delayed for as long as possible) with respect to patient and carer Quality of Life (QoL), control of the symptoms of PD (short and long term), safety and costs.

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)
Not Specified

Participant information sheet
Available in http://www.pdsurg.bham.ac.uk/documents/PISV4appd.pdf

Health condition(s) or problem(s) studied
Neurosciences, psychiatry

Interventions
Patients in both arms will receive active intervention:
1. In the surgery arm, Subthalamic nucleus stimulation (STN) surgery by stimulation (or possibly lesioning after the start up phase)

2. In the medical therapy arm, drugs will be prescribed as considered appropriate (this will often include continuous apomorphine)

Intervention Type
Other

Phase
Not Specified

Primary outcome measure
Patient's self-evaluation of functional status (using the PDQ-39 questionnaire). It is important that the trial assesses the patients' own perceptions of their functioning and addresses matters of most concern to them. The PDQ-39 is a self-completed questionnaire, specifically developed and tested for use in clinical trials by two of the applicants/collaborators. It reflects patients' concerns in eight aspects of PD: mobility, activities of daily living, emotional well-being, stigma, social support, cognition and bodily discomfort. It has been extensively tested for validity, reproducibility and sensitivity. Affective and cognitive changes are detected by PDQ-39

Secondary outcome measures
1. Quality of life. In addition to PDQ-39, the EuroQoL EQ-5D will be used as the main outcome measure for the Health Economic evaluation (see below) as this permits incremental quality adjusted life-years (QALYs) to be calculated.
2. Dementia screen. The trial aims to determine whether therapies prevent or decrease the decline of cognitive function as measured by the DRS-II. The DRS has the ability to assess the level of cognitive impairment in different clinical populations and to differentiate between types of dementia.
3. Clinical assessment of functioning. The Unified Parkinson's Disease Rating Scale (UPDRS - both on and off drug therapy) and Hoehn & Yahr staging system will provide a standard neurological assessment against which to validate further the PDQ-39 in a subset of patients.
4. Neuropsychology. A semi-structured neuropsychiatric interview and psychometric measures of depression/anxiety, and cognition (pre-morbid/current IQ, language, attention-executive functions, memory and spatial skills) in a subset of patients.
5. Burden on carers. Little is known about the effects of PD and its treatment on carers. The person identified by the patient as their primary carer, if they have one, will be asked to complete the SF36, a well validated measure of health status.
6. Institutionalisation rates and other measures of individual and societal cost.
7. Toxicity and side-effects of surgery, including mortality, stroke and other serious adverse events. Toxicity and side-effects of medical therapy will also be recorded.
8. Death from all causes and specifically from PD and the surgical procedure. Patients will be flagged with the Office for National Statistics (ONS) for long-term mortality follow-up.
Some centres will wish to undertake additional investigations (e.g. more detailed clinical assessments, including video records, neuropsychology, physiology and imaging) and we will encourage such scientific add-on studies, although they will not be part of the main trial.

Overall study start date
01/10/2001

Completion date
30/09/2011

Eligibility

Key inclusion criteria
1. They have PD that is not controlled by current medical therapy
2. They are considered fit enough for surgical intervention
3. They are unlikely to be considered to definitely require, and be able to receive, surgery within 1 year of entry
4. They are not demented
5. They are able to understand and complete the trial questionnaires (non-English speaking patients may be entered if they have a carer, relative or other person who can help them)
6. They have given written informed consent

Definite indications for, or contraindications against, any of the therapies in the trial are not specified by the protocol, but by the responsible clinician. Eligibility will be based on the 'uncertainty principle'.

Participant type(s)
Patient

Age group
Not Specified

Sex
Not Specified

Target number of participants
400-600. Closed to recruitment - in follow-up

Key exclusion criteria
Not provided at time of registration

Date of first enrolment
01/10/2001

Date of final enrolment
30/09/2011

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Department of Clinical Neurology
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Sponsor information

Organisation
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Sponsor type
University/education

Website
http://www.bham.ac.uk/

ROR
https://ror.org/03angcq70

Funder(s)

Funder type
Research council

Funder Name
Medical Research Council (MRC) (UK)

Alternative Name(s)
Medical Research Council (United Kingdom), UK Medical Research Council, MRC

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

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

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/06/2010		Yes	No