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Unilateral randomised double-blind placebo-controlled continuation of existing open-labelled intraputaminal GDNF (glial derived neurotrophic factor) infusion study for 6-months in subjects with idiopathic Parkinsons disease

Submission date
12/09/2003

Registration date
12/09/2003

Last Edited
23/09/2009

Recruitment status
No longer recruiting

Overall study status
Completed

Condition category
Nervous System Diseases

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

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
N0234120876

Study information

Scientific Title

Study objectives
The open-labelled trial has to date established the long term safety and therapeutic benefits of chronic intraputaminal GDNF infusion in the five patients with Parkinson's disease. This trial aims to assess the clinical effect of unilateral randomised double-blinded placebo controlled cessation of GDNF for 6-months. Unilateral cessation of GDNF infusion may result in either contralateral stability or a reduction of the improved clinical state.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not provided at time of registration

Study design
Randomised double blind placebo controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet

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

Interventions
Unilateral randomised double-blind placebo controlled study.

Intervention Type
Other

Phase
Phase I

Primary outcome measure
1. Unified Parkinson's disease Rating Scores (UPDRS) - total and lateralised scores.
2. Timed motor tests.
3. Patient diary assessments.
4. Quality of life measures - PDQ-39 and SF-36.
5. Change in medication requirement. 18F-dopa positron emission tomography (PET) changes.
6. Safety assessments.

Secondary outcome measures
Not provided at time of registration

Overall study start date
01/03/2003

Completion date
01/10/2003

Eligibility

Key inclusion criteria
Five patients currently enrolled in the open labelled study.

Participant type(s)
Patient

Age group
Adult

Sex
Not Specified

Target number of participants
5

Key exclusion criteria
Does not meet inclusion criteria

Date of first enrolment
01/03/2003

Date of final enrolment
01/10/2003

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Department of Neurology
Bristol
United Kingdom
BS16 1ND

Sponsor information

Organisation
Department of Health (UK)

Sponsor details
Richmond House
79 Whitehall
London
United Kingdom
SW1A 2NL

Sponsor type
Government

Website
http://www.doh.gov.uk

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
North Bristol NHS Trust (UK)

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	01/02/2005		Yes	No