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Randomised controlled trial of memantine versus placebo in Parkinson's disease dementia

Submission date	Recruitment status	[_] Prospectively registered
08/09/2005	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
14/09/2005	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
05/08/2009	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
3

Study information

Scientific Title

Study objectives
To investigate the safety and efficacy of memantine used for treatment of cognitive and functional impairment in Parkinson's disease.

Ethics approval required
Old ethics approval format

Ethics approval(s)
(Added 05/08/09) North Manchester Regional Ethics Committee (NMREC) gave approval on the 20th November 2003 (ref: 03/NM/359)

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

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

Interventions
Memantine, a new glutamatergic modulator used for treatment of cognitive and functional impairment in Alzheimer disease versus placebo.

Intervention Type
Drug

Phase
Not Specified

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

Primary outcome measure
Neuropsychological function including measures of:
1. Global cognitive impairment with emphasis on subcortical functions as assessed by the Dementia Rating Scale (DRS)(Mattis, 1988). This scale examines five areas including: attention, initiation and perseveration, construction, conceptual ability, and memory (verbal and visual).
2. Psychomotor speed and tracking as assessed by Trail Making Test, Part A and B (TMT) (Reitan, 1958).
3. Executive function as assessed by verbal fluency (Monsch et al., 1994).

Secondary outcome measures
1. Parkinsonian motor symptoms as measured by:
1.1. The Unified Parkinsons Disease Rating Scale, motor subscore (items 18-31)(UPDRS-motor) (Fahn et al., 1987) for assessment of baseline and change in motor symptoms. This will administered during the on phase or no sooner than 30minutes after administration of anti-Parkinsonian medications.
1.2. The Hoehn-Yahr Scale (HYS)(the same as UPDRS, Part V(Hoehn and Yahr, 1967) for assessment of stage of motor severity in PD (range 0 for no signs of disease to 5 wheelchair bound or bedridden).
2. Psychiatric symptoms as measured by:
2.1. Neuropsychiatric Inventory (NPI)(Cummings et al., 1994).
2.2. Cornell Depression Rating Scale (CDRS)(Alexopolous, 1988).
2.3. Hamilton Rating Scale for Depression (Hamilton 1960).
3. Functional ability as measures by the Parkinsons Disease Questionnaire (PDQ-39) (Jenkinson et al., 1998).
4. Global measure of change as assessed by the Clinicians Interview Based Impression of Change (CIBIC+).

Overall study start date
01/01/2005

Completion date
01/01/2007

Eligibility

Key inclusion criteria
1. Male and female patients, minimum age of 50.
2. Have a clinical diagnosis of idiopathic Parkinsons disease (PD) according to the UK Parkinsons Disease Society Brain Bank clinical diagnostic criteria (Daniel and Lees, 1993), in the mild to moderate stage as defined by Hoehn and Yahr stage < V (Hoehn and Yahr, 1967).
3. Have a clinical diagnosis of PDD, according to DSM-IV criteria (Code 294.1), with onset of symptoms of dementia at least 1 year after the first onset of PD motor symptoms.
4. Have dementia within the range of MMSE 10-26.
5. Treatment of the motor aspects of the disease stable for at least one month prior to enrolling in the study.
6. Presence of a reliable caregiver or spouse to act as informant and monitor the study drug.
7. Stable medical history and general health.
8. Able to consent to the study, be cooperative, and able to ingest oral medication. Informed consent will be written, however, if the patient is incapable of giving written consent, their legally authorised representative must be able to provide this).

Participant type(s)
Patient

Age group
Senior

Sex
Both

Target number of participants
50

Key exclusion criteria
1. Patients known to have a sensitivity to NMDA receptor antagonists or who are currently on amantadine, ranitidine or cimetidine.
2. Presence of brain disease other than PD (such as vascular dementia, stroke) or history of neurosurgery.
3. Presence of severe medical disorders.
4. A disability that may prevent the patient from completing all study requirements (eg blindness, deafness).
5. Female patients of child-bearing potential.
6. Taken any cognitive enhancing agent, such as a cholinesterase inhibitor, during the four weeks prior to randomization.

Date of first enrolment
01/01/2005

Date of final enrolment
01/01/2007

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Park House
Manchester
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Sponsor information

Organisation
Manchester Mental Health and Social Care Trust (UK)

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Sponsor type
Hospital/treatment centre

Funder(s)

Funder type
Industry

Funder Name
Lundbeck Ltd £53,000 (study grant) plus £5,350 (laboratoty costs) = £58,350

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	15/06/2009		Yes	No