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A double-blind, placebo-controlled multicentre trial of memantine in patients with Parkinsons disease dementia or dementia with Lewy bodies

Submission date
06/04/2006

Recruitment status
No longer recruiting

Registration date
13/04/2006

Overall study status
Completed

Last Edited
04/08/2009

Condition category
Nervous System Diseases

[X] 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
MEMDLBPDD2005-2 ver.3

Study information

Scientific Title

Acronym
MEMDPDDLB

Study objectives
Dementia with Lewy bodies (DLB) accounts for 15% - 20% of late onset dementia whilst Parkinsons disease occurs in 1% of individuals over the age of 65; with at least 50% of these individuals developing symptoms of dementia (Parkinsons disease dementia - PDD). In addition to memory problems, people with these conditions experience persistent hallucinations, Parkinsonian symptoms, marked problems with attention and fluctuating consciousness. Other symptoms that occur commonly include repeated falls, faints, temporary loss of consciousness, delusions and rapid eye movement (REM) sleep behaviour disorder.

Memantine is a safe and efficient treatment for cognitive and motor symptoms in patients with Parkinson's disease dementia (PDD) and patients with dementia with Lewy bodies (DLB)

Please note that, as of 30/09/2008, the anticipated end date of this trial has been amended from 29/02/2008 to 28/02/2009 (wrong date was entered on 24/09/2008).

Please note that, as of 24/09/2008, the end date of this trial has been updated from 01/06/2008 to 29/02/2008.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics approval received from the Regional Committees for Medical Research Ethics (REK) on the 7th November 2005 (ref: 210.05).

Study design
Multicentre double-blind placebo-controlled study

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
Parkinsons disease dementia or dementia with Lewy bodies

Interventions
Memantine versus placebo

Added as of 24/09/2008: Recruitment has been completed. Seventy-five patients were randomised.

Intervention Type
Drug

Phase
Not Specified

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

Primary outcome measure
Clinician's global impression of change (CGIC)

Secondary outcome measures
1. Mini-mental state examination
2. Alzheimers quick test
3. Cognitive drug research test
4. Neuropsychiatric inventory
5. Unified Parkinsons disease rating scale
6. Epworth sleepiness scale and Stavanger scale
7. Activities of daily living
8. Disability assessment for dementia
9. Quality of life assessment
10. Mayo fluctuation scale

Overall study start date
01/06/2006

Completion date
28/02/2009

Eligibility

Key inclusion criteria
1. A diagnosis of PD (Larsen, Dupont et al. 1994) and PD-dementia (Diagnostic and Statistical Manual of Mental Disorders - Fourth Edition [DSM IV] (1987, 1994) or DLB (McKeith et al. Neurol 2005)
2. Mild-to-moderate or moderate dementia (i.e. mini mental state examination MMSE 12-26, inclusive)
3. The subject has given a written informed consent
4. The subject is able and willing to comply with the study procedures and has a reliable caregiver (i.e. relative or nurse/nurse assistant who sees the patient at least weekly

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
74

Key exclusion criteria
1. Other brain disease of sufficient severity to cause dementia
2. Mental retardation
3. Terminal illness with life expectancy shorter than six months
4. Recent major changes in health status
5. Known epilepsy or previous convulsive seizure
6. Major depression
7. Severe dementia as defined by MMSE score of 12 or lower
8. Moderate to severe renal impairment (i.e. serum creatinine >1.5 upper limit normal (ULN) or creatinine clearance <40 ml per minute/1.73 m^2)
9. Moderate or severe heart disease (New York Heath Association [NYHA] III-IV)
10. Moderate to severe pulmonary disease
11. Moderate to severe hepatic impairment (bilirubin or transaminases >2 times ULN)
12. Women of childbearing potential (i.e. not post-menopausal and not taking contraceptive)
13. The subjects is lactating
14. Any laboratory value(s) exceeding the limits of normality if deemed to be clinically relevant by the study physician
15. Known allergies to the investigational product

Date of first enrolment
01/06/2006

Date of final enrolment
28/02/2009

Locations

Countries of recruitment
Norway

Sweden

United Kingdom

Study participating centre
Stavanger University Hospital
Stavanger

Norway
4095

Sponsor information

Organisation
Stavanger Helseforskning AS (Norway)

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Sponsor type
Research organisation

ROR
https://ror.org/009vyay43

Funder(s)

Funder type
Research organisation

Funder Name
Stavanger Helseforskning AS (Norway)

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	01/07/2009		Yes	No