

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	☒ Prospectively registered
Registration date 13/04/2006	Overall study status Completed	☐ Protocol
Last Edited 04/08/2009	Condition category Nervous System Diseases	☐ Statistical analysis plan
		☒ Results
		☐ Individual participant data

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

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Additional identifiers

Protocol serial number

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 Parkinson's disease occurs in 1% of individuals over the age of 65; with at least 50% of these individuals developing symptoms of dementia (Parkinson's 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).

Primary study design

Interventional

Study design

Multicentre double-blind placebo-controlled study

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Parkinson's 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(s)

Clinician's global impression of change (CGIC)

Key secondary outcome(s)

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

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

Healthy volunteers allowed

No

Age group

Adult

Sex

All

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 m²)
9. Moderate or severe heart disease (New York Heart 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

United Kingdom

Norway

Sweden

Study participating centre

Stavanger University Hospital

Stavanger

Norway

4095

Sponsor information

Organisation

Stavanger Helseforskning AS (Norway)

ROR

<https://ror.org/009vyay43>

Funder(s)

Funder type

Research organisation

Funder Name

Stavanger Helseforskning AS (Norway)

Results and Publications

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