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Memantine for the long term management of neuropsychiatric symptoms in Alzheimer's disease

Submission date	Recruitment status	[X] Prospectively registered
08/01/2008	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
14/02/2008	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
20/06/2016	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

Protocol serial number
Protocol Version 4, 8/7/2007

Study information

Scientific Title
Memantine for the Long Term Management of Neuropsychiatric Symptoms in Alzheimer's disease (MAIN-AD)

Acronym
MAIN-AD

Study objectives
The principal research objective is to investigate the efficacy and safety of memantine when compared to neuroleptics in the long-term management of neuropsychiatric symptoms in people with Alzheimer's disease.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Multi-centre Research Ethics Committee for Wales, 28/03/2008, ref: 08/MRE09/5

Primary study design
Interventional

Study design
Multi-centre double-blind placebo-controlled double-dummy parallel-group randomised controlled trial

Study type(s)
Treatment

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

Interventions
Intervention group: Memantine + placebo neuroleptic for 24 weeks
Control group: Neuroleptic + placebo memantine for 24 weeks

The choice of neuroleptic and dose will be made by the responsible clinician. The neuroleptics allowed are haloperidol, risperidone, olanzapine and quetiapine.

Intervention Type
Drug

Phase
Not Applicable

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

Primary outcome(s)
The following will be assessed at baseline, week 6, week 12 and week 24:
1. Bristol Activities of Daily Living scale. Please note that only the week 24 outcome will be

considered as the primary outcome.
2. Cohen-Mansfield agitation inventory.

Key secondary outcome(s)
The following will be assessed at baseline, week 6, week 12 and week 24:
1. Neuropsychiatric inventory
2. Severe impairment battery
3. Mini-mental state examination
4. Letter fluency (FAS) test
5. Functional assessment staging
6. Modified D test
7. Clinical global impression of change
8. Modified unified Parkinson's disease rating scale
9. Abnormal involuntary movement scale

Completion date
01/06/2010

Eligibility

Key inclusion criteria
1. Living in a nursing or social care facilities
2. Fulfill the National Institute of Neurological and Communication Disorders and Stroke/ Alzheimer's Disease and Related Disorders Association (NINCDS/ADRDA) criteria for possible or probable Alzheimer's Disease (AD)
3. Taking at least 0.5 mg daily of haloperidol, 0.5 mg daily of risperidone, 5 mg daily of olanzapine or 25 mg daily of quetiapine or another neuroleptic which in the opinion of the responsible clinician could be safely converted to one of these neuroleptics, for a minimum of 3 months prior to entry into the study
4. If taking a cholinesterase inhibitor, prescribed for at least 6 months before the date of assessment, with a stable dose for at least 3 months
5. Not taking anticonvulsants other than carbamazepine or sodium valproate. The use of either of these 2 agents is permissible if the dose has been stable for at least 4 weeks
6. If taking any other psychotropic drugs (e.g., antidepressants, benzodiazepines, chlormethiazole), the dose has been stable for at least 4 weeks prior to randomization
7. Have not received memantine in the last 6 weeks
8. Taking any medications that are contra-indicated or not recommended in combination with memantine, as defined in the British National Formulary, including ketamine, dextromethorphan and amantidine
9. Written informed consent provided by the participant (if they have capacity) and/or their next of kin or a legal representative

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
All

Key exclusion criteria
1. Current evidence of delirium
2. Moderately severe renal impairment, as measured by or equivalent to an estimated creatinine clearance of <50 mL/min/1.73 m2
3. Severe hepatic impairment
4. Unable to swallow tablets or capsules
5. Low probability of treatment compliance
6. Currently taking memantine
7. Previous evidence of lack of efficacy or tolerability to memantine
8. Taking any of the following substances:
8.1. An investigational drug during the 4 weeks prior to randomization
8.2. A drug known to cause major organ system toxicity during the 4 weeks prior to randomization.
8.3. Started any new psychotropic medication during the 4 weeks prior to randomization. Participants who have been on a stable dose of psychotropic during the 4 weeks prior to randomization are still eligible
8.4. Memantine during the 6 weeks prior to randomization
8.5. Other N-methyl-D-aspartate (NMDA) antagonists: amantadine, ketamine, and dextromethorphan.
8.6. Barbiturates and primidone
8.7. Baclofen and dantrolen
8.8. Dextromethorphan
8.9. Antimuscarinics
8.10. Anticonvulsants other than sodium valproate or carbamazepine. These 2 agents are permissible if doses have been stable for at least 4 weeks

Date of first enrolment
01/04/2008

Date of final enrolment
01/06/2010

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
King's College London
London
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Sponsor information

Organisation
King's College London (UK)

ROR
https://ror.org/0220mzb33

Funder(s)

Funder type
Industry

Funder Name
Lundbeck Pharmaceutical (Contact: Dr Ya'acov Leigh, Lundbeck House, Caldecotte Lake Business Park, Caldecotte, Milton Keynes, MK7 8LG, UK. E-mail: YALE@lundbeck.com)

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	01/04/2015		Yes	No