

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

Submission date 08/01/2008	Recruitment status No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered
Registration date 14/02/2008	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 20/06/2016	Condition category Nervous System Diseases	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Prof Clive Ballard

Contact details
Wolfson Centre for Age-Related Diseases
Wolfson Wing
Hodgkin Building
King's College London
Guy's Campus
London
United Kingdom
SE1 1UL
+44 20 7848 8054
clive.ballard@kcl.ac.uk

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

United Kingdom

SE1 1UL

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