

Memantine for AGitation in Dementia

Submission date 30/08/2006	Recruitment status No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered
Registration date 03/10/2006	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 22/10/2012	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
Dr Chris Fox

Contact details
Folkestone Health Centre
15-25 Dover Road
Folkestone
Kent
United Kingdom
CT20 1JY
+44 (0) 1303 228 836
DrChris.Fox@ekentmht.nhs.uk

Additional identifiers

Clinical Trials Information System (CTIS)
2005-005087-93

ClinicalTrials.gov (NCT)
NCT00371059

Protocol serial number
EUDRACT-2005-005087-93

Study information

Scientific Title

Acronym

MAGD

Study objectives

Does memantine have efficacy in agitation for dementia?

Ethics approval required

Old ethics approval format

Ethics approval(s)

South East Medical Research Ethics Committee will be looking at trial protocol on the 13/9/06 (reference number: 06/MREO1/82).

Study design

Pragmatic randomised controlled trial

Primary study design

Interventional

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Alheimers Disease

Interventions

Memantine versus placebo

Intervention Type

Drug

Phase

Not Specified

Drug/device/biological/vaccine name(s)

Memantine

Primary outcome(s)

CMAI at six weeks.

Key secondary outcome(s)

1. NeuroPsychiatric Inventory (NPI) score at six and 12 weeks
2. CMAI score at 12 weeks
3. Clinical Global Impressions (CGI) scale and Scales of Independent Behavior (SIB) score at six and 12 weeks
4. Quality of Life scale in Alheimers Disease (QOL-AD) at six and 12 weeks
5. Use of co-prescribed medication

6. Occasions of need to use trial rescue protocol mechanism of keeping patients in the trial during dose titration period up to week three

Completion date

03/01/2009

Eligibility

Key inclusion criteria

1. Residential/inpatients
2. Alzheimers-McKhann Criteria and Haschinski less than four
3. Mini-Mental State Examination (MMSE) score less than or equal to 19
4. Clinically significant agitation requiring treatment
5. Cohen-Mansfield Agitation Inventory (CMAI) score more than or equal to 45
6. Aged 55 years or more

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Senior

Sex

All

Key exclusion criteria

1. Memantine use in four weeks prior
2. On cholinesterase inhibitors for less than three months and dose not stable
3. Anti-psychotic, antibiotic, anti-epileptic, anti-depressant, benzodiazepine, lithium, or hypnotic dose alteration in two weeks prior to start
4. Antiparkinsonian medication
5. Hypersensitivity to memantine or components
6. Severe renal impairment
7. Epilepsy, history of convulsions or seizure, or receiving anti-epileptics
8. Concomitant usage of N-Methyl-D-Aspartic acid (NMDA) antagonists amantadine, ketamine, dextromethorphan
9. Recent Myocardial Infarction (MI), uncompensated Congestive Cardiac Failure (CCF) and uncontrolled hypertension
10. Severe, unstable or poorly controlled medical illness
11. Disability which affects ability to complete study
12. Active malignancy
13. Delirium, pain or medical illness as a cause of agitation
14. Any important drug interactions prohibited during study and in 14 days prior: analgesic (dextromethorphan), dopaminergics (amantadine, warfarin)

Date of first enrolment

03/01/2007

Date of final enrolment

03/01/2009

Locations

Countries of recruitment

United Kingdom

England

Study participating centre

Folkestone Health Centre

Kent

United Kingdom

CT20 1JY

Sponsor information

Organisation

East Kent Hospitals Research and Development Committee (UK)

ROR

<https://ror.org/02dqqj223>

Funder(s)

Funder type

Industry

Funder Name

Lundbeck Pharmaceuticals (UK)

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	01/06/2012		Yes	No