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Memantine for AGitation in Dementia

Submission date 30/08/2006	**Recruitment status** No longer recruiting	[X] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 03/10/2006	**Overall study status** Completed	
Last Edited 22/10/2012	**Condition category** 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

ClinicalTrials.gov (NCT)
NCT00371059

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

Protocol serial number
EUDRACT-

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).

Primary study design
Interventional

Study design
Pragmatic randomised controlled trial

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Alzheimers 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 Alzheimers 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. Antiparkinsonsian 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 (dextromethorpan), 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