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A Randomised Placebo Controlled Trial of a Cholinesterase Inhibitor in the Management of Agitation in Dementia that is Unresponsive to a Psychological Intervention

Submission date
21/09/2000

Recruitment status
No longer recruiting

Registration date
21/09/2000

Overall study status
Completed

Last Edited
07/09/2009

Condition category
Nervous System Diseases

[X] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

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)
NCT00142324

Protocol serial number
G0100070

Study information

Scientific Title

Acronym
CALM-AD Trial

Study objectives
To determine whether risperidone or donepezil are significantly better than placebo respectively in the management of agitation in AD that has not responded to, or is inappropriate for a standardized brief psychosocial treatment (BPST).

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not provided at time of registration

Primary study design
Interventional

Study design
Randomised controlled trial

Study type(s)
Not Specified

Health condition(s) or problem(s) studied
Neurosciences, psychiatry

Interventions
Randomised to receive:
1. Risperidone 0.5-1.0 mg
2. Donepezil 5-10mg
3. Placebo
For 12 weeks.

Intervention Type
Drug

Phase
Not Specified

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

Primary outcome(s)
A reduction in score on the Cohen Mansfield Agitation Inventory.

Key secondary outcome(s)
Not provided at time of registration

Completion date
30/04/2006

Eligibility

Key inclusion criteria
1. Probable or possible Alzheimer's disease (AD)
2. Clinically significant agitation
3. Age >39 years
4. Resident in care facility or community resident with carer
5. Not receiving treatment with neuroleptics or chlornesterase inhibitors
6. Carer with capacity to consent.

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Not Specified

Sex
Not Specified

Key exclusion criteria
1. Known sensitivity to donepezil or resperidone
2. Severe, unstable or uncontrolled medical conditions apparent from history, physical examination or investigations
3. Current evidence of delirium
4. Patient meets criteria for Probable Dementia with Lewy Bodies (McKeith et al, 1996)
5. Low probability of treatment compliance

Date of first enrolment
01/11/2003

Date of final enrolment
30/04/2006

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Division of Psychological Medicine
London
United Kingdom
SE5 8AF

Sponsor information

Organisation
King's College London (UK)

ROR
https://ror.org/0220mzb33

Funder(s)

Funder type
Research council

Funder Name
Medical Research Council (MRC) (UK)

Alternative Name(s)
Medical Research Council (United Kingdom), UK Medical Research Council, Medical Research Committee and Advisory Council, MRC

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

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	04/10/2007		Yes	No