

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	<input checked="" type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 21/09/2000	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 07/09/2009	Condition category Nervous System Diseases	<input type="checkbox"/> Individual participant data

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

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Contact details

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

NCT00142324

Secondary identifying numbers

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

Study design

Randomised controlled trial

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Not specified

Study type(s)

Not Specified

Participant information sheet

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 measure

A reduction in score on the Cohen Mansfield Agitation Inventory.

Secondary outcome measures

Not provided at time of registration

Overall study start date

01/11/2003

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 cholinesterase inhibitors
6. Carer with capacity to consent.

Participant type(s)

Patient

Age group

Not Specified

Sex

Not Specified

Target number of participants

285

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

England

United Kingdom

Study participating centre

Division of Psychological Medicine

London

United Kingdom

SE5 8AF

Sponsor information

Organisation

King's College London (UK)

Sponsor details

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ceu@kcl.ac.uk

Sponsor type

University/education

Website

<http://www.kcl.ac.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, MRC

Funding Body Type

Government organisation

Funding Body Subtype

National government

Location

United Kingdom

Results and Publications

Publication and dissemination plan

Not provided at time of registration

Intention to publish date**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