# 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	<b>Recruitment status</b> No longer recruiting	[X] Prospectively registered
		☐ Protocol
Registration date 21/09/2000	Overall study status Completed	Statistical analysis plan
		[X] Results
<b>Last Edited</b> 07/09/2009	Condition category Nervous System Diseases	[] Individual participant data

#### Plain English summary of protocol

Not provided at time of registration

#### Contact information

### Type(s)

Scientific

#### Contact name

Dr Robert Howard

#### Contact details

Division of Psychological Medicine Institute of Psychiatry De Crespigny Park London United Kingdom SE5 8AF

#### 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

#### Study design

Randomised controlled trial

#### Primary study design

Interventional

#### 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, 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 typeDetailsDate createdDate addedPeer reviewed?Patient-facing?Results articleresults04/10/2007YesNo