

A reliable assessment of the efficacy and safety of donepezil and aspirin in Alzheimer's Disease

Submission date 06/11/2002	Recruitment status No longer recruiting	☐ Prospectively registered
Registration date 06/11/2002	Overall study status Completed	☐ Protocol
Last Edited 28/10/2022	Condition category Nervous System Diseases	☐ Statistical analysis plan
		☒ 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

Study information

Scientific Title

A reliable assessment of the efficacy and safety of donepezil and aspirin in Alzheimer's Disease

Acronym

AD2000

Study objectives

To assess the efficacy and safety of donepezil and aspirin in Alzheimer's Disease.

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)

Treatment

Health condition(s) or problem(s) studied

Alzheimer's disease

Interventions

Patients are randomised to receive donepezil 5 mg or placebo for the first 12 weeks of the trial.

Those who complete 12 weeks of treatment are re-randomised to receive 48 weeks of donepezil or placebo from week 13 onwards, with donepezil dose sub-randomised between 5 and 10 mg.

Eligible patients (those with no clear indication for, or clear indication against, aspirin) are also randomised at entry between 75 mg enteric-coated aspirin daily or aspirin avoidance.

Intervention Type

Drug

Phase

Not Applicable

Drug/device/biological/vaccine name(s)

Donepezil, aspirin

Primary outcome(s)

1. Cognition (assessed with the mini-mental state examination [MMSE])
2. Functional ability (assessed with the Bristol activities of daily living scale [BADLS])

Patients were assessed at 12-week intervals in the first year and once each year thereafter.

Key secondary outcome(s)

1. Time to formal domiciliary or institutional care
2. Progress of disability
3. Behavioural symptoms

4. Caregiver wellbeing
5. Care time

Patients were assessed at 12-week intervals in the first year and once each year thereafter.

Completion date

01/01/2004

Eligibility

Key inclusion criteria

1. Diagnostic and Statistical Manual of Mental Disorders, Fourth edition (DSM IV) diagnosis of Alzheimer's disease, with or without evidence of vascular dementia
2. Mild to moderate Alzheimer's disease (Mini Mental State Examination [MMSE] score 10 - 26)
3. No definite contraindication to, or clear indication for, donepezil
4. Not in residential care
5. Regular carer
6. Not have already taken donepezil or any other cholinergic enhancing agent

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Not Specified

Sex

All

Key exclusion criteria

Not provided at time of registration

Date of first enrolment

01/01/2000

Date of final enrolment

01/01/2004

Locations

Countries of recruitment

United Kingdom

England

Study participating centre

University of Birmingham Clinical Trials Unit
Birmingham
United Kingdom
B15 2RR

Sponsor information

Organisation
West Midlands NHS Research & Development Executive (UK)

Funder(s)

Funder type
Government

Funder Name
West Midlands NHS Research & Development Executive (UK)

Results and Publications

Individual participant data (IPD) sharing plan
Not provided at time of registration

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	Study website	26/06/2004		Yes	No
Results article		01/01/2008		Yes	No
Study website		11/11/2025	11/11/2025	No	Yes