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

Submission date	Recruitment status	[ ] Prospectively registered
06/11/2002	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
06/11/2002	Completed	[X] Results
Last Edited	**Condition category**	[ ] Individual participant data
28/10/2022	Nervous System Diseases	

Plain English summary of protocol
Not provided at time of registration

Study website
http://www.ad2000.bham.ac.uk/

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

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

Study design
Randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet

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 measure
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.

Secondary outcome measures
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.

Overall study start date
01/01/2000

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

Age group
Not Specified

Sex
Both

Target number of participants
310

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
England

United Kingdom

Study participating centre
University of Birmingham Clinical Trials Unit
Birmingham
United Kingdom
B15 2RR

Sponsor information

Organisation
West Midlands NHS Research & Development Executive (UK)

Sponsor details
Bartholomew House
142 Hagley Road
Birmingham
United Kingdom
B16 9PA

Sponsor type
Government

Website
http://www.doh.gov.uk/research/wmro/new.htm

Funder(s)

Funder type
Government

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

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

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		26/06/2004		Yes	No
Results article		01/01/2008		Yes	No