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Efficacy of donepezil in the posterior variant of Alzheimer's disease (posterior cortical atrophy) study

Submission date	Recruitment status	[ ] Prospectively registered
19/05/2010	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
19/05/2010	Completed	[X] Results
Last Edited	**Condition category**	[ ] Individual participant data
17/01/2019	Nervous System Diseases	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
4159

Study information

Scientific Title
Efficacy of DONepezil in the Posterior variant of Alzheimer's Disease (posterior cortical atrophy) study

Acronym
DONIPAD

Study objectives
This is a single-centre, double-blind, placebo-controlled, cross-over study to assess the efficacy of donepezil in patients with the posterior variant of Alzheimer's disease.

This trial aims to identify the objective neuropsychological benefit of donepezil in patients with the posterior variant of Alzheimer's disease. There have been no previous studies to assess the effectiveness of donepezil in the posterior variant of Alzheimer's disease. Clinical observation suggests that this group may respond particularly well to cholinesterase inhibitors.

Ethics approval required
Old ethics approval format

Ethics approval(s)
MREC approved, ref: 03N025

Study design
Single-centre randomised interventional treatment trial

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Topic: Dementias and Neurodegenerative Diseases Research Network; Subtopic: Dementia; Disease: Dementia

Interventions
Patients will have baseline mini-mental state examination and neuropsychological tests for specific occipito-parietal functions. Patients will be randomised to receive donepezil 5 mg or placebo once daily for 6 weeks.

They will then be reassessed before increasing the dose to 10 mg donepezil in the treatment arm for a further 6 weeks, or continuing placebo in the other arm. They will be assessed at the end of this period before discontinuing the study drug for a 2-week washout period.

Follow-up length: 6 months
Study entry: single randomisation only

Intervention Type
Drug

Phase
Not Applicable

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

Primary outcome(s)
Mini Mental State Examination, measured at 0 weeks and 6 weeks

Key secondary outcome(s))
1. Digit span
2. Letter cancellation speed test
3. Simple calculation test
4. VOSP dot counting test
5. VOSP number location test

Completion date
30/12/2011

Eligibility

Key inclusion criteria
1. Clinical diagnosis of posterior variant of Alzheimer's disease
2. Memory test score above the 5th percentile on neuropsychological assessment
3. Absence of other causes of cognitive impairment based on dementia screen investigations available
4. Male and female, lower age limit of 18 years

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

Key exclusion criteria
1. Significant neurological or psychiatric disease other than Alzheimer's disease
2. Significant systemic disease
3. Medications with the potential to affect cognition unless maintained on a stable dose for at least 3 months

Date of first enrolment
27/06/2003

Date of final enrolment
30/12/2011

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
The Institute of Neurology
London
United Kingdom
WC1N 3BG

Sponsor information

Organisation
University College London (UCL) (UK)

ROR
https://ror.org/02jx3x895

Funder(s)

Funder type
Industry

Funder Name
Eisai Ltd (UK)

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				

Results article		01/05/2018		Yes	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes