

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

Submission date 19/05/2010	Recruitment status No longer recruiting	☐ Prospectively registered
Registration date 19/05/2010	Overall study status Completed	☐ Protocol
Last Edited 17/01/2019	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

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

Primary study design

Interventional

Study design

Single-centre randomised interventional treatment trial

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