

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

<b>Submission date</b> 19/05/2010	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered
<b>Registration date</b> 19/05/2010	<b>Overall study status</b> Completed	<input type="checkbox"/> Protocol
<b>Last Edited</b> 17/01/2019	<b>Condition category</b> Nervous System Diseases	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
		<input type="checkbox"/> 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

**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