

# 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

### Contact name

Miss Jane Douglas

### Contact details

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## Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

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

## Secondary study design

Randomised controlled trial

## Study setting(s)

Hospital

## Study type(s)

Treatment

## Participant information sheet

Not available in web format, please use the contact details to request a patient information sheet

## 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 measure**

Mini Mental State Examination, measured at 0 weeks and 6 weeks

### **Secondary outcome measures**

1. Digit span
2. Letter cancellation speed test
3. Simple calculation test
4. VOSP dot counting test
5. VOSP number location test

### **Overall study start date**

27/06/2003

### **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

### **Age group**

Adult

**Lower age limit**

18 Years

**Sex**

Both

**Target number of participants**

Planned sample size: 20; UK sample size: 20

**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**

England

United Kingdom

**Study participating centre**

**The Institute of Neurology**

London

United Kingdom

WC1N 3BG

**Sponsor information****Organisation**

University College London (UCL) (UK)

**Sponsor details**

Gower Street

London

England

United Kingdom

WC1E 6BT

**Sponsor type**

University/education

**Website**

<http://www.ucl.ac.uk/>

**ROR**

<https://ror.org/02jx3x895>

## Funder(s)

**Funder type**

Industry

**Funder Name**

Eisai Ltd (UK)

## Results and Publications

**Publication and dissemination plan**

Not provided at time of registration

**Intention to publish date****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?
<a href="#">Results article</a>	results	01/05/2018		Yes	No