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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

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?
Results article	results	01/05/2018		Yes	No