# Homocysteine and B vitamins in cognitive impairment

Submission date	Recruitment status	<ul><li>Prospectively registered</li></ul>		
03/05/2005	No longer recruiting	☐ Protocol		
Registration date	Overall study status	Statistical analysis plan		
21/06/2005	Completed	[X] Results		
Last Edited	Condition category	Individual participant data		
14/09/2015	Mental and Behavioural Disorders			

## Plain English summary of protocol

Not provided at time of registration

# Contact information

# Type(s)

Scientific

#### Contact name

Prof A. David Smith

#### Contact details

Department of Pharmacology Mansfield Rd Oxford United Kingdom OX1 3QT +44 (0)1865 271883 david.smith@pharmacology.ox.ac.uk

# Additional identifiers

**EudraCT/CTIS** number

**IRAS** number

ClinicalTrials.gov number

Secondary identifying numbers

TP212

# Study information

#### Scientific Title

Homocysteine and B vitamins in cognitive impairment

#### Acronym

**VITACOG** 

#### **Study objectives**

Lowering plasma total homocysteine by increasing B vitamin supplements will slow the rate of shrinkage of the brain in subjects with mild cognitive impairment and reduce the rate of decline in cognitive test scores

## Ethics approval required

Old ethics approval format

#### Ethics approval(s)

Not provided at time of registration

#### Study design

Randomised controlled trial

#### Primary study design

Interventional

# Secondary study design

Randomised controlled trial

#### Study setting(s)

Not specified

# Study type(s)

Treatment

#### Participant information sheet

# Health condition(s) or problem(s) studied

Cognitive Impairment

#### **Interventions**

Two groups: placebo and treated with folic acid (0.8mg), vitamin B12 (0.5mg) and vitamin B6 (20mg) for two years.

Follow-up: telephone memory test at 30 months after start.

#### Intervention Type

Supplement

#### Phase

**Not Specified** 

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

Folic acid, vitamin B12 and vitamin B6

#### Primary outcome measure

- 1. Rate of shrinkage of whole brain and or brain regions assessed by volumetric MRI
- 2. Changes in performance on a variety of cognitive tests

# Secondary outcome measures

- 1. Trial recruitment procedures
- 2. Conversion to dementia

#### Overall study start date

01/04/2004

#### Completion date

31/03/2006

# **Eligibility**

#### Key inclusion criteria

Subjects with mild cognitive impairment 70 years and older

#### Participant type(s)

**Patient** 

# Age group

Senior

#### Sex

Both

#### Target number of participants

300

#### Key exclusion criteria

- 1. Dementia
- 2. Treatment with drugs for dementia
- 3. Active cancer
- 4. Vitamin B12 injections
- 5. Stroke within last three months
- 6. Inability to undergo Magnetic Resonance Imaging (MRI) scan

#### Date of first enrolment

01/04/2004

# Date of final enrolment

31/03/2006

# Locations

#### Countries of recruitment

England

**United Kingdom** 

Study participating centre University of Oxford Oxford United Kingdom OX1 3QT

# Sponsor information

## Organisation

University of Oxford (UK)

# Sponsor details

Medical Sciences Research Services John Radcliffe Hospital Oxford England United Kingdom OX3 9DU +44 (0)1865 222604 michael.halsey@admin.ox.ac.uk

#### Sponsor type

University/education

#### **ROR**

https://ror.org/052gg0110

# Funder(s)

# Funder type

Research council

#### **Funder Name**

Medical Research Council (MRC) (UK) (TP212)

# Alternative Name(s)

Medical Research Council (United Kingdom), UK Medical Research Council, MRC

# **Funding Body Type**

Government organisation

# Funding Body Subtype

National government

#### Location

**United Kingdom** 

#### Funder Name

Charles Wolfson Charitable Trust

# **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	08/09/2010		Yes	No
Results article	results	01/07/2015		Yes	No