ISRCTN94410159 https://doi.org/10.1186/ISRCTN94410159

Homocysteine and B vitamins in cognitive impairment

Submission date	Recruitment status
03/05/2005	No longer recruiting
Registration date	**Overall study status**
21/06/2005	Completed
Last Edited	**Condition category**
14/09/2015	Mental and Behavioural Disorders

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[X] 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

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
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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