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Older People and Enhanced Neurocognitive function study

Submission date	Recruitment status	[X] Prospectively registered
03/03/2008	No longer recruiting	[X] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
04/04/2008	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
03/07/2015	Nervous System Diseases	

Plain English summary of protocol
Not provided at time of registration

Study website
http://www.open-study.org.uk

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

NO5R0009

Study information

Scientific Title
Older People and Enhanced Neurocognitive function study

Acronym
OPEN

Study objectives
Older people are at increased risk of vitamin B12 deficiency, which can lead to severe neurocognitive deficit (e.g., progressive weakness, vision and hearing loss, impairment in communication and co-ordination). The aim of the present study is to assess whether increased dietary intake of crystalline vitamin B12 will improve nerve function and cognitive function in older people with defined low vitamin B12 status. Demonstrating that vitamin B12 dependant nerve and cognitive function impairment is present even in individuals without clinical symptoms will have considerable public health significance.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Cambridgeshire 4 REC, 30/04/2008

Study design
Randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Patient information can be found at: http://openstudy.lshtm.ac.uk/participant.pdf

Health condition(s) or problem(s) studied
Nerve and cognitive function

Interventions
Daily nutritional supplement of 1 mg vitamin B12 versus placebo. The total duration of treatment is 12 months for both arms. Longer term follow-up may be the subject of a separate protocol.

Intervention Type
Supplement

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Vitamin B12 supplementation

Primary outcome measure
Amplitude of tibial motor evoked responses and tibial nerve conduction velocity, measured at 12 months.

Secondary outcome measures
1. Cognitive function: immediate recall, prospective memory, letter search/cancellation, verbal fluency, symbol digit modalities, simple and choice reaction time
2. Timed up and go
3. Psychological health (mood) using the 30-item General Health Questionnaire (GHQ-30)
4. Height and weight
5. History of myocardial infarction (MI) and stroke (reported hospitalisation)

All outcomes measured at 12 months.

Overall study start date
01/07/2008

Completion date
01/11/2010

Eligibility

Key inclusion criteria
1. Healthy volunteers
2. Aged 75 years and over, either sex
3. Defined low B12 status (greater than 107 pmol/l and less than 210 pmol/l)
4. No previous history of diabetes or dementia

Participant type(s)
Healthy volunteer

Age group
Senior

Sex
Both

Target number of participants
200

Key exclusion criteria

1. Pre-existing type I or type II diabetes at baseline
2. Pre-existing dementia at baseline
3. Currently consuming vitamin B12 on a daily basis
4. Mini-Mental State Examination (MMSE) score less than 24 at baseline screen
5. Very low B12 (below 107 pmol/l - Beckman Coulter assay)
6. B12 levels above 210 pmol/l
7. Anaemic
8. History of epilepsy
9. Those with implanted metallic devices such as a pacemaker
10. Alcoholics

Date of first enrolment
01/07/2008

Date of final enrolment
01/11/2010

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
London School of Hygiene and Tropical Medicine (LSHTM)
London
United Kingdom
WC1E 7HT

Sponsor information

Organisation
London School of Hygiene and Tropical Medicine (LSHTM) (UK)

Sponsor details
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Sponsor type
Hospital/treatment centre

Website
http://www.lshtm.ac.uk/

ROR
https://ror.org/00a0jsq62

Funder(s)

Funder type
Government

Funder Name
Food Standards Agency (UK)

Alternative Name(s)
The Food Standards Agency, FSA

Funding Body Type
Private sector organisation

Funding Body Subtype
Other non-profit organizations

Location
United Kingdom

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?
Protocol article	protocol	11/03/2011		Yes	No
Results article	results	01/09/2015		Yes	No