

Older People and Enhanced Neurocognitive function study

Submission date 03/03/2008	Recruitment status No longer recruiting	☒ Prospectively registered ☒ Protocol
Registration date 04/04/2008	Overall study status Completed	☐ Statistical analysis plan ☒ Results
Last Edited 03/07/2015	Condition category Nervous System Diseases	☐ 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

Protocol serial number
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

Primary study design

Interventional

Study design

Randomised controlled trial

Study type(s)

Treatment

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(s)

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

Key secondary outcome(s)

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.

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

Healthy volunteers allowed

No

Age group

Senior

Sex

All

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

United Kingdom

England

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)

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

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	01/09/2015		Yes	No
Protocol article	protocol	11/03/2011		Yes	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes
Study website	Study website	11/11/2025	11/11/2025	No	Yes