ISRCTN17616323 https://doi.org/10.1186/ISRCTN17616323

Oral vitamin B12 supplementation and cognitive performance in elderly people

Submission date	Recruitment status
20/12/2005	No longer recruiting
Registration date	**Overall study status**
20/12/2005	Completed
Last Edited	**Condition category**
09/11/2007	Nutritional, Metabolic, Endocrine

[_] 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

Contact name
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title

Acronym
Brain12 study

Study objectives
Counteract the process of cognitive impairment in elderly people with mild vitamin B12 deficiency through oral supplementation with vitamin B12 or a combination of vitamin B12 with folic acid

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics approval received from the local medical ethics committee

Study design
Randomised, double blinded, placebo controlled, parallel group 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
Vitamin B12 deficiency

Interventions
1. 1,000 microgram vitamin B12/day
2. 1,000 microgram vitamin B12 and 400 microgram folic acid/day
3. Placebo

Intervention Type
Supplement

Phase
Not Specified

Drug/device/biological/vaccine name(s)
Vitamin B12, folic acid

Primary outcome measure
Cognitive performance.

Secondary outcome measures
Blood biochemistry.

Overall study start date
01/05/2003

Completion date
31/10/2004

Eligibility

Key inclusion criteria
1. Men and women aged 70 years or older
2. Mild vitamin B12 deficiency defined as vitamin B12 concentration between 100 and 300 picomol/L and MMA concentration greater than 0.32 micromol/L and creatinine concentration less than 120 micromol/L

Participant type(s)
Patient

Age group
Senior

Sex
Both

Target number of participants
195

Key exclusion criteria
1. Severe cognitive impairment
2. Anemia
3. Gastrointestinal surgery
4. Use of vitamin B12 injections or supplements containing > 50 micrograms vitamin B12 and/or 25 micrograms folic acid
5. Less than 90% compliance during a 2 week placebo run in period
6. No written informed consent
7. Participation in other studies

Date of first enrolment
01/05/2003

Date of final enrolment
31/10/2004

Locations

Countries of recruitment
Netherlands

Study participating centre
Wageningen University,
Wageningen
Netherlands
6700 EV

Sponsor information

Organisation
The Netherlands Organisation for Health Research and Development (ZonMw) (Netherlands)

Sponsor details
P.O. Box 93245
Den Haag
Netherlands
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+31 (0)70 349 5111
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Sponsor type
Research organisation

Website
http://www.zonmw.nl

ROR
https://ror.org/01yaj9a77

Funder(s)

Funder type
Charity

Funder Name
Nutricia Research Foundation (The Netherlands)

Alternative Name(s)

Funding Body Type
Private sector organisation

Funding Body Subtype
Trusts, charities, foundations (both public and private)

Location
Netherlands

Funder Name
European Union BIOMED (Europe)

Funder Name
Kelloggs' Benelux (Belgium)

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	01/08/2006		Yes	No