

Oral vitamin B12 supplementation and cognitive performance in elderly people

Submission date
20/12/2005

Recruitment status
No longer recruiting

☐ Prospectively registered

☐ Protocol

Registration date
20/12/2005

Overall study status
Completed

☐ Statistical analysis plan

☒ Results

Last Edited
09/11/2007

Condition category
Nutritional, Metabolic, Endocrine

☐ Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Dr Simone Eussen

Contact details
Wageningen University,
Division of Human Nutrition
P.O. Box 8129
Wageningen
Netherlands
6700 EV
+31 (0)317 485395
simone.eussen@wur.nl

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

2509 AE

+31 (0)70 349 5111

info@zonmw.nl

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