Oral vitamin B12 supplementation and cognitive performance in elderly people.

Gepubliceerd: 09-09-2005 Laatst bijgewerkt: 18-08-2022

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.

Ethische beoordeling	Positief advies
Status	Werving gestopt
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON24656

Bron
Nationaal Trial Register

Verkorte titel
Brain12 study

Aandoening

Mild vitamin B12 deficiency.

Ondersteuning

Primaire sponsor: ZON-MW.
Overige ondersteuning: 1. Nutricia Research Foundation;
2. Kelloggs' Benelux;
3. Foundation to promote reseach into functional vitamin B12 deficiency and the European Union BIOMED Demonstration project.

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Cognitive performance.

Toelichting onderzoek

Achtergrond van het onderzoek

Mild vitamin B12 deficiency is highly prevalent in old age.
Reasons for this high prevalence are not fully understood but include atrophic gastritis and bacterial overgrowth which affect the ability to absorb crystalline vitamin B12 (e.g. the form found in fortified foods or vitamin pills) remains inctact in old age.
In both healthy and cognitively impaired elderly people associations between vitamin B12 status and cognitive performance have been observed, and the follow up of geriatric patients suggests effects of perenteral treatment in early cognitive impairment.

We investigated whether daily oral supplementation with 1,000 microgram vitamin B12 of 1,000 microgram vitamin B12 with 400 microgram folic acid for 24 weeks improves cognitive performance in people over 70 years with vitamin B12 deficiency.

Doel van het onderzoek

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.

Onderzoeksopzet

N/A

Onderzoeksproduct en/of interventie

1. 1,000 microgram vitamin B12/day;

2. 1,000 microgram vitamin B12 + 400 microgram folic acid/ day;

3. Placebo.

Contactpersonen

Publiek

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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 > 0.32 micromol/L and creatinine concentration < 120 micromol/L.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

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. < 90% compliance during a 2 week placebo run in perfiod;

6. No written informed consent;

7. Participation in other studies.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Dubbelblind
Controle:	Placebo

Deelname

Nederland

Status:	Werving gestopt
(Verwachte) startdatum:	01-05-2003
Aantal proefpersonen:	195
Type:	Werkelijke startdatum

Ethische beoordeling

Positief advies

Datum:	09-09-2005
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL274
NTR-old	NTR312
Ander register	: N/A
ISRCTN	ISRCTN17616323

Resultaten

Samenvatting resultaten
1. Clin Chem Lab Med 2005; 43(3): A20
2. J Nutr. Health and Aging 2005; 9(3):148
 3. Haematologica Reports 2005; 1(3):49
4. Am J Clin Nutr. 2006 Aug;84(2):361-70.
