Vitamin B12 and Folic Acid Supplementation for Preventing Fractures in Elderly People

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Supplementation with 500 µg vitamin B12 and 400 µg folic acid reduces fracture incidence in elderly people.

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

Samenvatting

ID

NL-OMON24934

Bron
Nationaal Trial Register

Verkorte titel
B-PROOF

Aandoening

osteoporosis
fracture
cognitive decline
physical performance
quality of life
nutritional status

Ondersteuning

Primaire sponsor: Wageningen University, Divison of Human Nutrition
Overige ondersteuning: ZonMw: The Netherlands Organisation for Health Research and Development
NZO: Dutch Dairy Association
MCO Health
Wageningen University

Erasmus Medical Center
VU University Medical Center

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Fracture incidence

Toelichting onderzoek

Achtergrond van het onderzoek

It is hypothesized that vitamin B12 and folic acid supplementation reduces the number of incident fractures. The B-PROOF study, a randomized placebo-controlled intervention trial, compares daily supplementation with folic acid (400 µg) and vitamin B12 (500 µg) to a placebo for a period of two years or longer in 2919 men and women aged 65 years and older, with initial basal plasma total homocysteine (tHcy) levels ≥ 12 µmol/L. Fracture incidence and time to fracture were assessed and used as the efficacy measure.
The data showed that combined vitamin B12 and folic acid supplementation had no effect on osteoporotic fracture incidence in this elderly population. Exploratory subgroup analyses suggest a beneficial effect on osteoporotic fracture prevention in compliant persons aged .80 y. However, treatment was also associated with increased incidence of

cancer, although the study was not designed for assessing

cancer outcomes. Therefore, vitamin B-12 plus folic acid

supplementation cannot be recommended at present for

fracture prevention in elderly people

Doel van het onderzoek

Supplementation with 500 µg vitamin B12 and 400 µg folic acid reduces fracture incidence in elderly people.

Onderzoeksopzet

screening

baseline

final measurements

Onderzoeksproduct en/of interventie

- 500 µg vitamin B12 and 0.4 mg folic acid in one capsule, once per day

- placebo capsule, once per day

Contactpersonen

Publiek

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

1. 65 years and older; based on entry date into study;
2. Fasting plasma Hcy level >= 12 µmol/L and < 50 µmol/L;
3. No current or recent (<4 months) use of supplements with very high doses of B-vitamins;
4. Competent to make own decisions;
5. Persons with skin cancer are allowed to participate;
6. Compliance to tablet intake > 85%;
7. Serum creatinine >150 µmol/L.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

1. Participation in other intervention trials;

2. Serious medical conditions, e.g. cancer diagnosis within the last 5 years or recent myocardial infarction;

3. Immobilization (bedridden, wheelchair bound)

Onderzoeksopzet

Opzet

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

Deelname

Nederland

Status:	Werving gestopt
(Verwachte) startdatum:	01-07-2008
Aantal proefpersonen:	3000
Type:	Werkelijke startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nog niet bepaald

Ethische beoordeling

Positief advies

Datum:	01-06-2008
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	NL1287
NTR-old	NTR1333
Ander register	6130.0031 : BV PROOF 07/30
ISRCTN	ISRCTN wordt niet meer aangevraagd

Resultaten

Samenvatting resultaten

- Design paper:

Van Wijngaarden JP, Dhonukshe-Rutten RAM, van Schoor NM, van der Velde N, Swart KMA, Enneman AW, van Dijk SC, Brouwer-Brolsma EM, Zillikens MC, van Meurs JBJ, Brug J, Uitterlinden AG, Lips P, de Groot LCPGM. Rationale and design of the B-PROOF study, a randomized controlled trial on the effect of supplemental intake of vitamin B12 and folic acid on fracture incidence. BMC Geriatr 2011;11:80

- Van Wijngaarden JP, Swart KMA, Enneman AW, Dhonukshe-Rutten, van Dijk SC, Brouwer-Brolsma EM, van der Zwaluw NL, Sohl E, van Meurs JBJ, Zillikens MC, van Schoor NM, van der Velde N, Brug J, Uitterlinden AG, Lips P, de Groot LCPGM. Effect of daily vitamin B12 and folic acid supplementation on fracture incidence in elderly with an elevated plasma homocysteine level: B-PROOF, a randomized controlled trial. Am J Clin Nutr 2014; 100(6):1578-1586.

- Paper with main outcomes:
