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

No registrations found.

Ethical review	Positive opinion
Status	Recruitment stopped
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON24934

Source
NTR

Brief title
B-PROOF

Health condition

osteoporosis
fracture
cognitive decline
physical performance
quality of life
nutritional status

Sponsors and support

Primary sponsor: Wageningen University, Divison of Human Nutrition
Source(s) of monetary or material Support: ZonMw: The Netherlands Organisation for Health Research and Development
NZO: Dutch Dairy Association
MCO Health
Wageningen University
Erasmus Medical Center
VU University Medical Center

Intervention

Outcome measures

Primary outcome

Fracture incidence

Secondary outcome

- falls

- quantitative ultrasound (QUS)

- bone turnover

- BMD

- incidence of cardiovascular events or diagnosis of cancer

- physical performance

- cognitive decline

- quality of life

Study description

Background summary

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

Study objective

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

Study design

screening

baseline

final measurements

Intervention

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

- placebo capsule, once per day

Contacts

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Eligibility criteria

Inclusion criteria

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.

Exclusion criteria

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)

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Placebo

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-07-2008
Enrollment:	3000
Type:	Actual

IPD sharing statement

Plan to share IPD: Undecided

Ethics review

Positive opinion

Date:	01-06-2008
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
NTR-new	NL1287
NTR-old	NTR1333
Other	6130.0031 : BV PROOF 07/30
ISRCTN	ISRCTN wordt niet meer aangevraagd

Study results

Summary results
- 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:
