

Is long-term use of proton pump inhibitors associated with vitamin B12 deficiency in elderly individuals?

Published: 03-07-2006

Last updated: 14-05-2024

Is long-term PPI-use associated with low vitamin B12 levels in old age?

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Vitamin related disorders
Study type	Observational invasive

Summary

ID

NL-OMON29864

Source

ToetsingOnline

Brief title

PPIs and vitamin B12 deficiency in the elderly

Condition

- Vitamin related disorders

Synonym

cobalamin deficiency, low vitamin B12 serum levels

Research involving

Human

Sponsors and support

Primary sponsor: Leids Universitair Medisch Centrum

Source(s) of monetary or material Support: Ministerie van OC&W, SCAL diagnostisch en facilitair centrum

Intervention

Keyword: Aged, Proton pump inhibitors, Vitamin B12 (deficiency)

Outcome measures

Primary outcome

We will compare serum vitamin B12, folic acid and homocysteine between the two study groups.

Results will be adjusted for possible differences in nutritional behavior and status, health status, use of vitamin supplements and helicobacter pylori status.

Secondary outcome

We will compare hemoglobin levels and mean corpuscular volume between the two study groups.

Study description

Background summary

Many elderly individuals use proton pump inhibitors (PPIs) for gastro-esophageal reflux disease (GERD), peptic ulcer and chronic use of NSAIDs. However, PPIs inhibit the formation of gastric acid in the stomach. Gastric acid is essential for the release of vitamin B12 from food. Long-term PPI-use might therefore lead to vitamin B12 deficiency in the elderly.

Study objective

Is long-term PPI-use associated with low vitamin B12 levels in old age?

Study design

Blood parameters will be compared between long-term PPI-users (> 3 years) of 65 years and older (N=110) and their partners (N=110).

Study burden and risks

Burden: PPI-users and partners visit the lab or are visited by a trained employee from the lab. 6 mL blood is drawn from every participant. Additionally, every participant is asked to fill in a short questionnaire on nutritional status, use of medication (incl. vitamin supplements), and other demographic characteristics.

Risk: The collection of small blood samples is standard procedure in medical practice. The risk of study participation is therefore small.

Benefit: The general practitioner will be informed on the lab results. In case of abnormal lab values, the general practitioner might initiate treatment.

Contacts

Public

Leids Universitair Medisch Centrum

Postbus 2088
2301 CB Leiden
Nederland

Scientific

Leids Universitair Medisch Centrum

Postbus 2088
2301 CB Leiden
Nederland

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age

Adults (18-64 years)

Elderly (65 years and older)

Inclusion criteria

Individuals of 65 years and older that have had at least 810 Defined Daily Doses (DDD) of proton pump inhibitors in the last three years and live with their partner.

Exclusion criteria

A couple will be excluded from study participation if the general practitioner indicates that one of the following characteristics apply to the user of proton pump inhibitors or partner:

- vitamin B12 supplementation
- folic acid supplementation
- use of H2-blockers
- use of antacids
- known chronic alcohol abuse
- cognitive impairment

A couple will also be excluded when the partner uses proton pump inhibitors.

Study design

Design

Study type:	Observational invasive
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Prevention

Recruitment

NL	
Recruitment status:	Recruitment stopped
Start date (anticipated):	01-07-2006
Enrollment:	220
Type:	Actual

Ethics review

Approved WMO

Application type:

First submission

Review commission:

METC Leiden-Den Haag-Delft (Leiden)

metc-ldd@lumc.nl

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

CCMO

NL11916.058.06