The effect of vitamin B12 supplementation on fatigue in IBS and IBS patients.

Published: 16-04-2010
Last updated: 02-05-2024

To study the effectiveness of vitamin B12 supplementation on decreasing fatigue in IBD and IBS patients with increased or severe fatigue and normal vitamin B12 levels.

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Other condition
Study type	Interventional

Summary

ID

NL-OMON34980

Source
ToetsingOnline

Brief title
B-VIT study

Condition

- Other condition

Synonym
low energy, Tiredness

Health condition

Vermoeidheid

Research involving
Human

Sponsors and support

Primary sponsor: Wageningen Universiteit
Source(s) of monetary or material Support: Maatschap Internisten en MDL-artsen;ziekenhuis Gelderse Vallei

Intervention

Keyword: Fatigue, Inflammatory bowel disease, Irritable bowel syndrome, Vitamin B12

Outcome measures

Primary outcome

Difference in mean change of fatigue score between the treatment and control

group after 8 weeks.

Secondary outcome

Differences in QoL and depression scores between treatment and control group

after 8 weeks.

Study description

Background summary

Fatigue is a major problem in general medical practice, and is one of the most common symptoms mentioned by patients. Fatigue can be defined as extreme and persistent tiredness, weakness or exhaustion both mentally and physically. The prevalence of fatigue in general practice ranges from 5% to 10 %. It is demonstrated that fatigue is a common nonspecific symptom in patients with Irritable Bowel Syndrome (IBS) as well as in patients with Inflammatory Bowel Disease (IBD).

Although no sufficient evidence is available in literature, high dosage of vitamin B12 supplementation is used for the treatment of fatigue in non conventional therapy/medicine. Gastroenterologists are sceptical about this treatment. However, after a short intervention with vitamin B12 injections in IBD and IBS patients with fatigue and a normal vitamin B12 level 70% experienced improvement (subjective benefit) of their fatigue. Furthermore, in an ongoing study (IDeaL) in 697 patients with IBS and IBD it was shown that supplement use in both groups was very high, respectively 44% and 40%, compared

to 27% in the general Dutch population. This excessive use of supplements may increase health care costs, since more medication are used. Beside, more money is spend in non conventional medicine than in regular medicine. So far, no studies have been conducted which demonstrate the effect of extra contribution of vitamin B12 on fatigue in IBS and IBD patients.

Furthermore, quality of life (QoL) and depression are also general recognized problems in IBS and IBD patients. Though IBS is not a fatal disease, it can still have a serious impact on QoL and also IBD patients have lower QoL compared to the general population. Depression is also a common sign in these patient groups. Since fatigue, QoL and depression are closely related to each other it is interesting to study these outcome measures as an indicator of perceived health, after administration of extra vitamin B12.

Therefore, we would like to study the effect on fatigue, QoL and depression after a period of orally administered vitamin B12 in IBD and IBS patients who are experiencing fatigue and having normal serum B12 levels in a double-blind randomized placebo-controlled trial.

Study objective

To study the effectiveness of vitamin B12 supplementation on decreasing fatigue in IBD and IBS patients with increased or severe fatigue and normal vitamin B12 levels.

Study design

The proposed trial is a randomized double-blind placebo-controlled trial, with two parallel arms (placebo versus B12 supplement). In this study the effectiveness of oral supplementation with vitamin B12 will be assessed in the prevention of fatigue in subjects aged between 18 and 65 years old. This intervention will last for a period of 8 weeks and will include 80 patients.
The study will be performed in Gelderse Vallei Hospital.

Intervention

Two treatments are used in this double-blind, placebo-controlled trial with block randomization of subjects:
- 1000 µg (= 1 mg) vitamin B12, once per day
- Placebo tablet, once per day, with similar appearance
Patients will receive B12 tablet or placebo according to the group to which they are randomized.

Study burden and risks

No risks are expected, but unexpected effects like diarrhoea and exanthema,

could occur.
Burden is at a moderate level because the subjects have to take a capsule every day, fill out questionnaires and they have to keep a calendar during the 8-week study period. At baseline and at the end of the study blood is taken from the subjects.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

Diagnosed with IBS or IBD
Increased or severe fatigue for at least 3 months
Vitamin B12 level >=150 pmol/l
Normal haemoglobin levels

Exclusion criteria

Bowel resection
Prednisone therapy
Use of vitamin B12 injections in last 2 months
Use of B12 or iron supplements in last 2 months

Study design

Design

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	16-10-2010
Enrollment:	70
Type:	Actual

Ethics review

Approved WMO

Date:	16-04-2010
Application type:	First submission
Review commission:	METC Wageningen Universiteit (Wageningen)

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	NL31209.081.10