

Evaluation of vitamin B12 supplementation on nutritional status in vegan and vegetarian subjects

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| Submission date 04/04/2017 | Recruitment status No longer recruiting | <input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol |
| Registration date 28/04/2017 | Overall study status Completed | <input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results |
| Last Edited 15/08/2022 | Condition category Nutritional, Metabolic, Endocrine | <input type="checkbox"/> Individual participant data |

Plain English summary of protocol

Background and study aims

The vegetarian diet, or the stricter vegan diet, requires particular attention to any deficiency (shortage) in certain nutrients. In particular, vitamin B12 is present exclusively in animal products and is involved in many important reactions in the body. Vegans that exclude animal products from their diet may incur in a deficient nutritional status. The deficiency in the long term may lead to the onset of anemia (low blood iron) and neurological problems (issues with the brain, spine and nerves), as well as effects on the immune system (ability to fight off illness), hyperhomocysteinemia (an elevation of an amino acid in the blood that is linked to heart disease) and cognitive (mental) decline. In a situation where you people are unable to get enough B12 it is normal take supplements such as tablets that contain the nutrient. The aim of this study is to investigate the effect of the consumption of two different dosages (a high dose and a low dose) of vitamin B12 supplement sublingual tablets (a tablet that is inserted beneath the tongue to dissolve) in people with a marginal (low) deficiency.

Who can participate?

Vegan and vegetarian healthy adults aged 20-60 years old with a vitamin B12 deficiency.

What does the study involve?

Participants undergo a medical examination and complete questionnaires to determine eligibility. They are then randomly allocated to one of two groups. Those in the first group receive a low dose (350mcg/week) of a B12 dietary supplement (a tablet) that they take daily for three months. Those in the second group receive a high dose (2000mcg/week) of a vitamin B12 dietary supplement (a tablet) that they take weekly for three months (they take placebo pills the other six days of the week). Participants are followed up with blood samples before the study and at day 15, 30, 60 and 90 to monitor their nutritional levels and assess the concentration of the vitamin in their blood.

What are the possible benefits and risks of participating?

Participants may benefit from the expected improvement of vitamin B12 nutritional status. There is a slight risk of temporary headaches, balance problems or vision disorders associated with high dose supplements.

Where is the study run from?

University of Milano Department of Food, Environmental and Nutritional Sciences (Italy)

When is the study starting and how long is it expected to run for?

March 2015 to April 2017

Who is funding the study?

Phoenix SRL (Italy)

Who is the main contact?

1. Professor Salvatore Ciappellano (Scientific)

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2. Dr Antonella Brusamolino (Scientific)

Contact information

Type(s)

Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

11/15 University of Milano - ethical comitee

Study information

Scientific Title

Evaluation of nutritional status of vitamin B12 in vegans and vegetarians with marginal deficiency after 12 weeks of supplementation with two dosages of a sublingual formulation

Acronym

NuCbl

Study objectives

Dietary supplementation with low dose of vitamin B12 sublingually administered to vegan subjects should allow the recovery of an adequate nutritional status related to vitamin B12.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Ethics Committee of the University of Milan, 04/03/2015, ref: 11/15

Study design

12 week two armed dietary interventional randomised parallel trial

Primary study design

Interventional

Secondary study design

Randomised parallel trial

Study setting(s)

Community

Study type(s)

Quality of life

Participant information sheet

Not available in web format, please use the contact details below to request a patient information sheet

Health condition(s) or problem(s) studied

Healthy volunteers with B12 marginal deficiency

Interventions

Participants are enrolled in the study after they complete a specific questionnaire and medical examination to determine eligibility. Participants are then randomly allocated to one of two groups based on when they joined the study.

Control group (Hd- high dose): Participants are given a high vitamin B12 concentration (2000mcg /week) dietary supplement that they take weekly for three months. Supplements are given tablets that dissolve under the tongue. Participants in this group take tablets everyday but only once a week take a pill that is enriched with B12, the other six days the tablets are placebo.

Test group (Ld- low dose): Participants are given a low vitamin B12 concentration (350mcg /week) dietary supplement that they take daily for three months. Supplements are given as tablets that dissolve under the tongue and are taken daily.

Fasting blood samples (about 30 mL) are obtained from all participants, at baseline and after 15, 30, 60 and 90 days to assess Vitamin B12, holotranscobalamine, methylmalonic acid, homocysteine, folic acid, vitamin B6 and complete blood count. This is also done to monitor the modification of the nutritional status during the entire intervention.

Intervention Type

Supplement

Primary outcome measure

Nutritional status (vitamin B12, holotranscobalamin, methylmalonic and homocysteine concentrations) are measured using blood samples at baseline, day 15, day 30, day 60 and day 90

Secondary outcome measures

1. Complete blood count is measured using blood samples at baseline, day 15, day 30, day 60 and day 90
2. Serum levels of folic acid is measured using blood samples at baseline, day 15, day 30, day 60 and day 90
3. Vitamin B6 is measured using blood samples at baseline, day 15, day 30, day 60 and day 90

Overall study start date

12/02/2014

Completion date

10/04/2017

Eligibility

Key inclusion criteria

1. Healthy men/women (20-60 years of age)
2. Moderate smoking (about 5-6 cigarette/day)
3. Moderate physical activity (25-30 min per day of brisk walk or jog)
4. Moderate alcohol consumption (up to 14 drinks per week)
5. Plasma levels of vitamin B12 lower than 220 pmol / L
6. Follow a vegan diet
7. No regular intake of drugs (for any type of disease)
8. Non allergic subjects

Participant type(s)

Healthy volunteer

Age group

Adult

Sex

Both

Target number of participants

At least 40 subjects

Total final enrolment

40

Key exclusion criteria

1. History of cardiovascular, coronary, diabetes, hepatic, renal, or gastrointestinal diseases.
2. Use of any drugs, medications at least one month before the beginning of the experiment.
3. Use of vitamin B12 supplements at least one year before the beginning of the experiment.
4. Omnivore subjects

Date of first enrolment

05/05/2015

Date of final enrolment

04/12/2016

Locations**Countries of recruitment**

Italy

Study participating centre

University of Milan

Department of Food, Environmental and Nutritional Sciences

Via Celoria 2

Milano

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20133

Sponsor information

Organisation

Phoenix S.R.L. - LongLife Nutritional Supplements

Sponsor details

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Sponsor type

Industry

Website

www.longlife.it

Funder(s)

Funder type

University/education

Funder Name

University of Milan

Funder Name

Phoenix S.R.L. - LongLife Nutritional Supplements

Results and Publications

Publication and dissemination plan

Planned publication in a high-impact peer reviewed journal. Expected participation in conferences and public events to present the results.

Intention to publish date

31/12/2017

Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study are/will be available upon request from Salvatore Ciappellano salvatore.ciappellano@unimi.it

IPD sharing plan summary

Available on request

Study outputs

| Output type | Details | Date created | Date added | Peer reviewed? | Patient-facing? |
|---------------------------------|--|--------------|------------|----------------|-----------------|
| Results article | results | 01/04/2019 | | Yes | No |
| Results article | Association of cobalamin and vascular endothelial-cadherin in trial participants | 16/07/2022 | 15/08/2022 | Yes | No |