

Cobalamin deficiency in primary care: a placebo-controlled, double-blind, randomized trial

Submission date 29/12/2005	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
Registration date 20/02/2006	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 27/01/2011	Condition category Nutritional, Metabolic, Endocrine	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

Study information

Scientific Title

Study objectives

To evaluate the clinical and biological impact of oral vitamin B12 therapy among patients with a serum vitamin B12 level below 200 pmole/l

Ethics approval required

Old ethics approval format

Ethics approval(s)

The study was approved by the Ethical Review Committee for Clinical Research, Department of Internal Medicine, University of Lausanne, Switzerland

Study design

Placebo-controlled, double-blind, randomized trial

Primary study design

Interventional

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Cobalamin deficiency

Interventions

Oral vitamin B12 versus placebo

Intervention Type

Supplement

Phase

Not Specified

Drug/device/biological/vaccine name(s)

Oral vitamin B12

Primary outcome(s)

Evolution of biological markers (serum vitamin B12 level, serum methymalonic acid and homocystein levels)

Key secondary outcome(s)

Clinical evolution (hematologic, neurologic, psychiatric)

Completion date

31/12/2005

Eligibility

Key inclusion criteria

Patients suspected of cobalamin deficiency with serum vitamin B12 level between 125 and 200 pmole/l. Patients with serum vitamin B12 level below 125 pmole/l were followed-up openly with oral cobalamin.

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Sex

All

Key exclusion criteria

Unwillingness to participate

Date of first enrolment

01/01/2004

Date of final enrolment

31/12/2005

Locations**Countries of recruitment**

Switzerland

Study participating centre

Bugnon 44

Lausanne

Switzerland

1011

Sponsor information**Organisation**

Medical Outpatient Clinic, University of Lausanne (Switzerland)

ROR

<https://ror.org/019whta54>

Funder(s)**Funder type**

University/education

Funder Name

Medical Outpatient Clinic, University of Lausanne

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	13/01/2011		Yes	No