

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

<b>Submission date</b> 29/12/2005	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered
<b>Registration date</b> 20/02/2006	<b>Overall study status</b> Completed	<input type="checkbox"/> Protocol
<b>Last Edited</b> 27/01/2011	<b>Condition category</b> 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

**Contact name**  
Dr Bernard Favrat

**Contact details**  
Bugnon 44  
Lausanne  
Switzerland  
1011  
+41 (0)21 314 4906  
bernard.favrat@hospvd.ch

## Additional identifiers

**EudraCT/CTIS number**

**IRAS number**

**ClinicalTrials.gov number**

**Secondary identifying numbers**  
N/A

## 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

### **Secondary study design**

Randomised controlled trial

### **Study setting(s)**

Not specified

### **Study type(s)**

Treatment

### **Participant information sheet**

### **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 measure**

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

**Secondary outcome measures**

Clinical evolution (hematologic, neurologic, psychiatric)

**Overall study start date**

01/01/2004

**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

**Age group**

Adult

**Sex**

Both

**Target number of participants**

40 (20 in each group)

**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)

## Sponsor details

Bugnon 44

Lausanne

Switzerland

1011

+41 (0)21 314 4906

bernard.favrat@hospvd.ch

## Sponsor type

University/education

## ROR

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

# Funder(s)

## Funder type

University/education

## Funder Name

Medical Outpatient Clinic, University of Lausanne

# Results and Publications

## Publication and dissemination plan

Not provided at time of registration

## Intention to publish date

## 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?
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[Results article](#)

results

13/01/2011

Yes

No