ISRCTN22063938 https://doi.org/10.1186/ISRCTN22063938

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

Submission date	Recruitment status
29/12/2005	No longer recruiting
Registration date	**Overall study status**
20/02/2006	Completed
Last Edited	**Condition category**
27/01/2011	Nutritional, Metabolic, Endocrine

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] 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

Protocol serial number
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

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