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

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
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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?

Results article	results	13/01/2011	Yes	No