

# Effectiveness of ORAL hydroxocobalamin in treatment of vitamin B12 deficiency with neurological manifestations

<b>Submission date</b> 16/07/2011	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered
<b>Registration date</b> 02/09/2011	<b>Overall study status</b> Completed	<input type="checkbox"/> Protocol
<b>Last Edited</b> 21/01/2019	<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

### Background and study aims

Vitamin B12 (also known as cobalamin) is one of the eight B vitamins. It helps keep the body's nerve and blood cells healthy and helps make DNA. A low blood level of vitamin B12 (vitamin B12 deficiency) can cause neurological symptoms such as tingling, numbness, muscle weakness, difficulty walking properly, irritability, confusion and forgetfulness. Vitamin B12 deficiency is treated with intramuscular cobalamin (injected into a muscle). Some have suggested that cobalamin taken orally may be as effective, with the advantages of being easier to take and a lower cost. The effectiveness of oral vitamin B12 on severe neurological symptoms has not been confirmed to date and most doctors still recommend intramuscular cobalamin. The aim of this study is to assess the effectiveness of oral hydroxocobalamin (another form of vitamin B12) for the treatment of vitamin B12 deficiency with neurological symptoms.

### Who can participate?

Patients aged 18 to 80 with chronic (long-term) vitamin B12 deficiency with neurological symptoms

### What does the study involve?

Participants receive oral hydroxocobalamin daily for 10 days then after that once a month for 2 years. Blood vitamin B12 levels and neurological symptoms are measured before taking hydroxocobalamin and at day 10 and day 90.

### What are the possible benefits and risks of participating?

Not provided at time of registration

### Where is the study run from?

Hassan II Hospital (Morroco)

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

January 2011 to December 2013

Who is funding the study?  
Hassan II Hospital (Morroco)

Who is the main contact?  
Prof. Zouhayr Souirti

## Contact information

**Type(s)**  
Scientific

**Contact name**  
Prof Zouhayr Souirti

**Contact details**  
Lot 70  
Wafae 4  
Narjis  
Fez  
Morocco  
30000

## Additional identifiers

## Study information

**Scientific Title**  
Effectiveness of ORAL hydroxocobalamin in treatment of vitamin B12 deficiency with neurological manifestations: a single-centre, prospective, open-label study

**Acronym**  
ORAB

**Study objectives**  
Some investigators have suggested that oral cobalamin treatment may be as effective in the treatment of this condition, with the advantages of ease of administration and lower cost. All these investigators have used oral cyanocobalamin. In this prospective study we have administered oral hydroxocobalamin.

**Ethics approval required**  
Old ethics approval format

**Ethics approval(s)**  
Ethics Committee of Medicine and Pharmacy, Faculty of Fez, Hassan II Hospital, 21/07/2011

**Study design**  
Single-centre prospective open-label study

**Primary study design**

Interventional

## Study type(s)

Treatment

## Health condition(s) or problem(s) studied

Vitamin B12 deficiency

## Interventions

1. Oral hydroxocobalamin dose: 15000 ug/day (5000 X 3/day) is administered at days 1, 2, 3, 4, 5, 6, 7, 8, 9 and 10
2. After that 15000 ug/month (administered once every month)
3. Total duration of intervention: 2 years
4. Serum vitamin B12: day 0 (before taking hydroxocobalamin), day 10 (10th day of taking hydroxocobalamin), and day 90 (third month)
5. Follow up after 3 months

## Intervention Type

Drug

## Phase

Not Applicable

## Drug/device/biological/vaccine name(s)

Hydroxocobalamin

## Primary outcome(s)

Serum vitamin B12 level on days 10 and 90

## Key secondary outcome(s)

1. Haematological parameters : Hemoglobin level, mean corpuscular volume (MCV), reticulocyte number, white cells and platelets
2. Neurological improvement : questionnaires e.g. minimental state examination (MMSE), neurological exam with sense vibration tested by diapazon 128 Hz.  
Measured at days 10 and 90

## Completion date

30/12/2013

## Eligibility

### Key inclusion criteria

Presence of neurological signs due to vitamin B12 deficiency, unexplained by other causes, with a rate of serum vitamin B12 <200 pg / ml

### Participant type(s)

Patient

### Healthy volunteers allowed

No

**Age group**

Adult

**Sex**

All

**Key exclusion criteria**

1. Patients previously treated for vitamin B12 deficiency
2. Patients aged under 18 or over 80 years
3. Patients with vitamin B12 deficiency corrected without resorting to the long-term supplementation

**Date of first enrolment**

03/01/2011

**Date of final enrolment**

30/12/2013

**Locations****Countries of recruitment**

Morocco

**Study participating centre**

Lot 70

Fez

Morocco

30000

**Sponsor information****Organisation**

Hassan II Hospital (Morroco)

**ROR**

<https://ror.org/03m2nqg26>

**Funder(s)****Funder type**

Hospital/treatment centre

**Funder Name**

Hassan II Hospital (Morroco)

## 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?
<a href="#">Results article</a>	results	01/12/2016	21/01/2019	Yes	No