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Effectiveness of ORAl hydroxocobalamin in treatment of vitamin B12 deficiency with neurological manifestations

Submission date
16/07/2011

Recruitment status
No longer recruiting

Registration date
02/09/2011

Overall study status
Completed

Last Edited
21/01/2019

Condition category
Nutritional, Metabolic, Endocrine

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

Primary study design
Interventional

Study design

Single-centre prospective open-label study

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?
Results article	results	01/12/2016	21/01/2019	Yes	No