Clinical Trial Protocol
Iranian Registry of Clinical Trials
07 Sep 2019

The effect of vitamin B12 and folic acid supplementation on serum homocysteine, megaloblastic anemia status, blood pressure and life quality in patients with multiple sclerosis

Protocol summary

Summary
The goal of this study is to evaluate the effect of vitamin B12 and folate supplementation on serum homocysteine, megaloblastic anemia status, hypertension and life quality of M.S patients. This study is a double-blinded randomized clinical trial in which blinding will be conducted for the patients and the researcher. Patients will be divided into two groups (each group consists of 25 patients), including the intervention group and the placebo group. Both groups of patients will be selected randomly among relapsing-remitting M.S patients aged 20 - 40 years old. Exclusion criteria includes some conditions that can affect the variables in the study, like some nuerological disorders and vitamin B12 consumption during the last six months. Blood pressure, CBC blood test, serum homocysteine and life quality questionnaire will be measured in both groups before starting the interventions. Interventions in the intervention group consist of 5mg oral folate supplement (once a day) for two months and 3 doses of 1mg vitamin B12 injective supplement; the first dose will be injected immediately after taking blood samples from the patients, the second dose one month after the first injection, and the third dose one month after the second injection. And in placebo group, interventions include pills made from strach similar to folate supplement and normal saline injection (doses are similar to those of the intervention group). At the end of the interventions, CBC blood test, serum homocysteine level, Life quality and blood pressure, will be measured in both groups and the results will be analyzed.

General information

Acronym
IRCT registration information
IRCT registration number: IRCT2015100313678N7
Registration date: 2016-03-01, 1394/12/11
Registration timing: registered_while_recruiting

Registration date
2016-03-01, 1394/12/11

Registrant information
Name
Saeed Ghavamzadeh
Name of organization / entity
Urmia University of Medical Sciences
Country
Iran (Islamic Republic of)
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+98 44 1278 0803
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Recruitment status
Recruitment complete

Funding source
Private

Expected recruitment start date
2016-02-13, 1394/11/24

Expected recruitment end date
2016-03-05, 1394/12/15

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
The effect of vitamin B12 and folic acid supplementation on serum homocysteine, megaloblastic anemia status, blood pressure and life quality in patients with multiple sclerosis

Public title
The effect of vitamin B12 and folic acid supplementation on the treatment of multiple sclerosis

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria: patients with relapsing-remitting multiple sclerosis diagnosed with McDonald criteria; 20 to 40 age interval Exclusion criteria: other kind of
neurological diseases or severe depression; kidney disorders; patients with traumatic brain injuries; cardiovascular disease; vitamin B6, vitamin B12, folic acid, choline or betaine consumption during the last six months

Age
From 20 years old to 40 years old

Gender
Both

Phase
N/A

Groups that have been masked
None

Sample size
Target sample size: 50

Randomization (investigator’s opinion)
Randomized

Randomization description

Blinding (investigator’s opinion)
Double blinded

Blinding description

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids
empty

Ethics committees

1

Ethics committee

Name of ethics committee
Biomedical research ethics committee of Urmia University of Medical Sciences

Street address
Urmia University of Medical Sciences, Orjans valley, Resalat boulevard

City
Urmia

Postal code
Approval date
2016-01-05, 1394/10/15

Ethics committee reference number
IR.UMSU.REC.1394.316

Health conditions studied

1

Description of health condition studied
Multiple sclerosis

ICD-10 code
G35

ICD-10 code description
Multiple sclerosis

Primary outcomes

1

Description
Life quality

Timepoint
Before and after the intervention

Method of measurement
MSQOL-54 standard questionnaire, persian edition

2

Description
Serum homocysteine

Timepoint
Before and after the intervention

Method of measurement
Blood test

3

Description
Hemoglobin

Timepoint
Before and after the intervention

Method of measurement
Blood test

4

Description
MCV

Timepoint
Before and after the intervention

Method of measurement
Blood test

Secondary outcomes
empty

Intervention groups

1

Description
Folic acid 5mg oral supplement tablet once a day for intervention group

Category
Treatment - Drugs
2
Description
Vitamin B12 1mg injective supplement. injecting 3 doses of it during the study period in the intervention group. the first dose will be injected immediately after taking blood samples from the patients, the second dose a month after the first injection, and finally the third dose injection a month after the previous injection
Category
Treatment - Drugs

3
Description
Oral placebo tablets made of starch similar to folic acid once a day in the control group
Category
Placebo

4
Description
normal saline injection similar to vitamin B12 intervention, injecting 3 doses of it during the study period in the intervention group. the first dose will be injected immediately after taking blood samples from the patients, the second dose a month after the first injection, and finally the third dose injection a month after the previous injection
Category
Placebo

Recruitment centers
1
Recruitment center
Name of recruitment center
Kermanshah M.S society
Full name of responsible person
Ehsan Nozari
Street address
Licence plate 1, Dourisan valley, Pawe
City
Kermanshah

Sponsors / Funding sources
1
Sponsor
Name of organization / entity
Vice chancellor for research, Urmia University of Medical Sciences
Full name of responsible person
Saied Ghavamzadeh
Street address
Urmia University of Medical Sciences, Orjans valley, Resalat boulevard
City
Urmia
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Vice chancellor for research, Urmia University of Medical Sciences
Proportion provided by this source
100
Public or private sector
empty
Domestic or foreign origin
empty
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
empty
Person responsible for general inquiries
Contact
Name of organization / entity
Urmia University of Medical Sciences
Full name of responsible person
Saied Ghavamzadeh
Position
Associate Professor
Other areas of specialty/work

Person responsible for scientific inquiries
Contact
Name of organization / entity
Urmia University of Medical Sciences
Full name of responsible person
Saied Ghavamzadeh
Position
Associate Professor
Other areas of specialty/work

Person responsible for updating data
Contact
Name of organization / entity
Urmia University of Medical Sciences
Full name of responsible person
Saied Ghavamzadeh
Position
Associate Professor
Other areas of specialty/work
Street address
Sharing plan

Deidentified Individual Participant Data Set (IPD)
empty

Study Protocol
empty

Statistical Analysis Plan
empty

Informed Consent Form
empty

Clinical Study Report
empty

Analytic Code
empty

Data Dictionary
empty