Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

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**

Last update:

Update count: **0**

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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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
No information
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
Urima
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

5

Description
MCHC
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

Person responsible for scientific inquiries

Contact
Name of organization / entity
Urmia University of Medical Sciences
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Saied Ghavamzadeh
Position
Associate Professor
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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