

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 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 neurological 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 starch 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

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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

Full name of responsible person

Saied Ghavamzadeh

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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