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: empty
Update count: 0
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**
Double blinded

**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

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
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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
empty
Type of organization providing the funding
empty

Person responsible for general inquiries

Person responsible for scientific inquiries

Contact
Name of organization / entity
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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