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
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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
Country
Iran (Islamic Republic of)
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

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
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

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

Category
Placebo

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
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Licence plate 1, Dourisan valley, Pawe
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Sponsors / Funding sources

1
Sponsor
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Associate Professor
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Sharing plan
Deidentified Individual Participant Data Set (IPD)
empty

Study Protocol
eempty

Statistical Analysis Plan
eempty

Informed Consent Form
eempty

Clinical Study Report
eempty

Analytic Code
eempty

Data Dictionary
eempty