Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

Impact of "evidence based formulated multivitamin-mineral" supplementation on fatigue scale and serum level cytokines in multiple sclerosis

Protocol summary

Summary

Objective: effect of multivitamin-mineral on fatigue and inflammatory cytokines in multiple sclerosis patients Study Design: This study is a 3 blind randomized and interventional study. The study population and sample size: 100 multiple sclerosis patients participate in the study that are referred from multiple sclerosis clinics of ICNR and MS Sinai Research Center (joint project between two centers). Groups: 2 groups; 50 multiple sclerosis patients enter to interventional group and 50 multiple sclerosis patients enter to placebo group. Patients in intervention group are received Multivitamin Mineral for 3 months in manner of 2 tablets per day and Patients in control group are received placebo (microcrystalin cellulose + croscarmellose sodium) for 3 months in manner of 2 tablets per day Main inclusion criteria: Patients with Relapsing Remitting Multiple Sclerosis (RRMS); Patients must be at range of 18-45 years old; Patients should take every types of interferon for at least 3 months before the study; patients EDSS must be 0-6 Main exclusion criteria: abnormal serum ferritin, serum zinc, vitamin D / Patients with increasing in EDSS more than 1 unit during the study. The primary outcomes are fatigue and inflammatory and non-inflammatory cytokines serum levels and consequences outcome is depression.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016022026658N1**
Registration date: **2016-02-29, 1394/12/10**
Registration timing: **prospective**

Last update:
Update count: **0**

Registration date

2016-02-29, 1394/12/10

Registrant information

Name

Sama Bitarafan

Name of organization / entity

Iranian Center of Neurological Research/ Tehran University of Medical Sciences

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Cinnagen pharmaceutical companies (Related academic research with industry)

Expected recruitment start date

2016-04-20, 1395/02/01

Expected recruitment end date

2017-08-23, 1396/06/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Impact of "evidence based formulated multivitamin-mineral" supplementation on fatigue scale and serum level cytokines in multiple sclerosis

Public title

Impact of multivitamin on fatigue and inflammatory

cytokines in multiple sclerosis

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Patients with definite diagnosis of multiple sclerosis according to McDonald (2010) criteria; Patients with Relapsing Remitting Multiple Sclerosis (RRMS) as the clinical course of disease; Patients must be at range of 18-45 years old; Patients should take every types of interferon for at least 3 months before the study; Patients should not take any supplements from at least 3 months before the study; The fatigue score of patients must be 21-84 based on MFIS questionnaire; Patients should not take any antidepressant SSRI, modafinil, bupropion and Amurel at least 3 months before the study. patients EDSS must be 0-6 Exclusion criteria: Patients with definite diagnosis of severe liver disease, gallstones and pancreatitis, systemic diseases affecting the balance of Th1 / Th2 such as asthma and active viral disease, autoimmune diseases such as SLE and RA,inflammatory bowel disease, type I diabetes; Patients with abnormal result tests of serum ferritin, serum zinc, vitamin D; Patients with malnutrition (BMI less than 19) or obesity (BMI greater than 25); Patients with changes in drugs and diet during the study;); Patients with known allergic reactions to vitamin supplements; Patients with Pregnancy; Patients with alcohol or drug addiction and Smoking; Patients that forget to use of more than 12 days of supplements (10% of supplementation); Patients with increasing in EDSS more than 1 unit during the study.

Age

From **77 years** old to **49 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **100**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Triple blinded

Blinding description

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Tehran University of Medical Sciences

Street address

Keshavarz Boulevard, Central Building of Tehran University

City

Tehran

Postal code

(021) 88925072

Approval date

2015-10-04, 1394/07/12

Ethics committee reference number

IR.TUMS.REC.1394.873:شماره طرح: 27795 /شماره نامه

Health conditions studied

1

Description of health condition studied

Demyelinating diseases of the central nervous system

ICD-10 code

G35

ICD-10 code description

Multiple sclerosis

Primary outcomes

1

Description

IL 17

Timepoint

At first and end of study

Method of measurement

laboratory

2

Description

IF gama

Timepoint

At first and end of study

Method of measurement

laboratory

3

Description

CRP

Timepoint

At first and end of study

Method of measurement

laboratory

4

Description

Fatigue

Timepoint

At first and end of study

Method of measurement

MFIS, ESS Questionnaire

5

Description
IL 10
Timepoint
At first and end of study
Method of measurement
laboratory

Secondary outcomes

1

Description
Depression
Timepoint
At first and end of study
Method of measurement
Beck II questionnare

Intervention groups

1

Description
Multivitamin-mineral supplementation in intervention group
Category
Treatment - Other

2

Description
Administration of placebo with the same shape and packaging in control group
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Iranian Center of Neurological Research
Full name of responsible person
Dr Sama Bitarafan
Street address
Imam Khomeini Hospital, Iranian Center of Neurological Research
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Tehran

2

Recruitment center
Name of recruitment center
Sina MS research center
Full name of responsible person
Dr Sama Bitarafan
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Sinai Hospital/ Sina MS research center
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Sinagene Pharmaceutical Company/ Nano Hayat Daru
Full name of responsible person
Dr Behzad Taghipour
Street address
Pardis Technology Park/ 16 Avenue/ 168/2
City
Tehran
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Sinagene Pharmaceutical Company/ Nano Hayat Daru
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
Iranian Center of Neurological Research
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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