

Clinical Trial Protocol

Iranian Registry of Clinical Trials

21 Jul 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

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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	
<u>1</u>	
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 شماره طرح: 27795 / شماره نامه IR.TUMS.REC.1394.873
Health conditions studied	
<u>1</u>	
Description of health condition studied	Demyelinating diseases of the central nervous system
ICD-10 code	G35
ICD-10 code description	Multiple sclerosis
Primary outcomes	
<u>1</u>	
Description	IL 17
Timepoint	At first and end of study
Method of measurement	laboratory
<u>2</u>	
Description	IF gama
Timepoint	At first and end of study
Method of measurement	laboratory
<u>3</u>	
Description	CRP
Timepoint	At first and end of study
Method of measurement	laboratory
<u>4</u>	
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 questionnaire

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

City

Tehran

2

Recruitment center

Name of recruitment center

Sina MS research center

Full name of responsible person

Dr Sama Bitarafan

Street address

Sinai Hospital/ Sina MS research center

City

Tehran

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

Full name of responsible person

Dr Sama Bitarafan

Position

Assistant 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