Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Nov 2026

Effect of vitamin D on serum levels of CHI3L1 inflammatory factor and oxidative stress in patients with multiple sclerosis: a before-after clinical trial

Protocol summary

Study aim
To assess the effect of vitamin D on serum levels of CHI3L1 inflammatory factor and oxidative stress in patients with multiple sclerosis

Design
This is a before-after clinical trial without control group, phase III in which 35 patients with multiple sclerosis will be enrolled. Blinding is not possible in this study

Settings and conduct
This study will be performed in the Besat Hospital in Hamadan city on 35 eligible patients with multiple sclerosis. This is a before-after clinical trial therefore blinding is not possible in this study.

Participants/Inclusion and exclusion criteria
Inclusion criteria: Age of 18 to 65 years Women with multiple sclerosis Exclusion criteria: Acute infection Diabetes Rheumatoid diseases Kidney dysfunction Malabsorption Autoimmune diseases

Intervention groups
Intervention group: Oral vitamin D3 supplement with a dose of 50,000 units once a week for 8 weeks

Main outcome variables
Primary outcome: CHI3L1 serum level, serum level of oxidative stress factors

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20120215009014N473**
Registration date: **2023-05-11, 1402/02/21**
Registration timing: **prospective**

Last update: **2023-05-11, 1402/02/21**
Update count: **0**

Registration date
2023-05-11, 1402/02/21

Registrant information

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2023-05-22, 1402/03/01

Expected recruitment end date
2023-07-23, 1402/05/01

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Effect of vitamin D on serum levels of CHI3L1 inflammatory factor and oxidative stress in patients with multiple sclerosis: a before-after clinical trial

Public title
Effect of vitamin D on serum levels of CHI3L1 inflammatory factor and oxidative stress in patients with multiple sclerosis

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Age of 18 to 65 years Women with multiple sclerosis

Exclusion criteria:

Acute infection Diabetes Rheumatoid diseases Kidney dysfunction Malabsorption Autoimmune diseases

Age

From **18 years** old to **65 years** old

Gender

Female

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **35**

Randomization (investigator's opinion)

N/A

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Single

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Hamadan University of Medical Sciences

Street address

Vice-chancellor for Research and Technology, Hamadan University of Medical Sciences, Shahid Fahmideh Ave

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6517838695

Approval date

2023-02-05, 1401/11/16

Ethics committee reference number

IR.UMSHA.REC.1401.984

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

CHI3L1 serum level

Timepoint

Before the intervention and 8 weeks later

Method of measurement

Using ELISA kit

2

Description

Serum level of oxidative stress factors

Timepoint

Before the intervention and 8 weeks later

Method of measurement

Using ELISA kit

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Oral vitamin D3 supplement with a dose of 50,000 units once a week for 8 weeks

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Besat Hospital in Hamadan city

Full name of responsible person

Sevda Asadpour

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Sponsors / Funding sources

1

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Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Hamedan University of Medical Sciences
Proportion provided by this source
100
Public or private sector
Public
Domestic or foreign origin
Domestic
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
Academic

Person responsible for general inquiries

Contact
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be a plan to make this available

Study Protocol
Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan
Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form
Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report
Undecided - It is not yet known if there will be a plan to make this available

Analytic Code
Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary
Undecided - It is not yet known if there will be a plan to make this available