Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Comparing the effect of high dose vitamin D3 intake on interleukin-10, 17 and quality of life in Multiple Sclerosis patients

Protocol summary

Summary

Objectives: effect of high dose vitamin D3 intake vs placebo on interleukin-10, 17 and quality of life in Multiple Sclerosis patients Design: randomized clinical trial Study groups: intervention and placebo group Phase:1 phase, 3 months Sample size:40 for each group Blinding: The patient and laboratory staff where the blood samples are obtained remain blinded throughout the study. Randomization: Randomization is performed by selection from sealed envelopes. Setting and conduct: After giving informed consent, eligible patients are randomized to one of two groups. The study physician gives medication or placebo to the participant according to randomization and allocation. Participants including major eligibility criteria: Inclusion criteria: a definite diagnosis of Relapsing-remitting MS (RRMS) according to Mc Donald criteria؛ age 18 to 55 years؛ EDSS (Expanded Disability Status Scale) score of less than 4؛ no relapse 30 days before inclusion؛ negative β-HCG test for women in child bearing age. Exclusion criteria: pregnancy؛ lactation؛ any other disease than MS؛ receiving>4000IU/d vitamin D؛ past history of renal or hepatic disease؛ relapse during the study؛ received corticosteroids in the previous 30 days؛ Calcium (Ca)>11mg/dl؛ Aspartate Transaminase(AST) or Alanine Transaminase(ALT)>3 times normal values؛ alkaline phosphatase (ALP)>2.5 times normal values. Intervention:One group receives 50,000IU vitamin D every five days (Vitamin D Pearl, 50,000IU, Zahravi pharmaceutical Co., Tabriz, Iran). The other group receives placebo. main outcome measures: primary outcome variables: Interleukin 10, 17 secondary outcome variables: quality of life

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2015010910891N2**

Registration date: **2015-08-19, 1394/05/28**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2015-08-19, 1394/05/28

Registrant information

Name

Fereshteh Ashtari

Name of organization / entity

Isfahan University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 913 114 7644

Email address

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Recruitment status

Recruitment complete

Funding source

Isfahan University of Medical Sciences

Expected recruitment start date

2013-12-22, 1392/10/01

Expected recruitment end date

2014-05-15, 1393/02/25

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparing the effect of high dose vitamin D3 intake on interleukin-10, 17 and quality of life in Multiple Sclerosis patients

Public title

Comparing the effect of high dose vitamin D3 intake on interleukin-10, 17 and quality of life in Multiple Sclerosis patients

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria: a definite diagnosis of Relapsing-remitting Multiple Sclerosis (RRMS) according to Mc Donald criteria؛ age 18 to 55 years؛ EDSS (Expanded Disability Status Scale) score of less than 4؛ no relapse 30 days before inclusion؛ negative β-HCG test for women in child bearing age. Exclusion criteria: pregnancy؛ lactation؛ any other disease than Multiple Sclerosis؛ receiving>4000IU/d vitamin D؛ past history of renal or hepatic disease؛ relapse during the study؛ received corticosteroids in the previous 30 days؛ Calcium (Ca)>11mg/dl؛ Aspartate Transaminase(AST) or Alanine Transaminase(ALT)>3 times normal values؛ alkaline phosphatase (ALP)>2.5 times normal values.

Age
From **18 years** old to **55 years** old

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **45**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Double blinded

Blinding description

Placebo
Used

Assignment
Parallel

Other design features
Randomization is performed by selection from sealed envelopes.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of Isfahan University of Medical Sciences

Street address
Hezar jerib Street, Azadi Square

City
Isfahan

Postal code

Approval date
2013-12-20, 1392/09/29

Ethics committee reference number
192165

Health conditions studied

1

Description of health condition studied
Multiple sclerosis

ICD-10 code
G35

ICD-10 code description

Primary outcomes

1

Description
Interleukin 10, 17

Timepoint
At baseline and after 3 months

Method of measurement
Blood sample

Secondary outcomes

1

Description
Quality of life

Timepoint
3 months

Method of measurement
MSQOL54

Intervention groups

1

Description
Intervention group 1: 50,000IU vitamin D every five days, for 3 months vitamin D pearl Zahravi Pharmaceuticals

Category
Treatment - Drugs

2

Description
Control group: placebo tablet, including inert substance one every five days, made by a Pharmacist

Category
Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center
Kashani Hospital

Full name of responsible person

Fereshteh Ashtari

Street address

Beheshti Street, Kashani Hospital

City

Isfahan

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research, Isfahan University of Medical Sciences

Full name of responsible person

Payman Adibi

Street address

Hezar Jerib Street, Isfahan University of Medical Sciences

City

Isfahan

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, Isfahan 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

Type of organization providing the funding

empty

Person responsible for general inquiries

Contact

Name of organization / entity

Isfahan University of Medical Sciences

Full name of responsible person

Fereshteh Ashtari

Position

Professor in Neurology

Other areas of specialty/work

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Other areas of specialty/work

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Web page address

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