

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

The effect of vitamin D3 supplementation in the prevention of Optic Neuritis conversion to Multiple Sclerosis in patients with low serum vitamin D status after one year follow up: a randomized double blind clinical trial.

Protocol summary

Summary

In this trial, we aimed to evaluate the effect of vitamin D3 supplementation on preventing optic neuritis conversion to multiple sclerosis in patients with low serum vitamin D status (primary outcome) and to study the effects of this vitamin on patients' MRI lesions after 12 months (secondary outcome). In a double blind parallel groups (15 in each group; aged 20-40 years) randomized clinical trial, 30 optic neuritis patients with serum 25(OH)D level of less than 30 ng/ml who did not fulfill the 2005 McDonald Criteria for multiple sclerosis, were enrolled. The treatment group, received 50000 IU/week of vitamin D3 and the control group received a placebo for 12 months. Patients who demonstrated poor compliance with instructions to take vitamin D or placebo, or who failed to attend for follow-up visits, MRI scanning and vitamin D measurements during the study, were excluded. Finally, the rate of subsequent relapses(s) and any changes in the MRI lesions were compared between two groups.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201205319919N1**

Registration date: **2012-06-23, 1391/04/03**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2012-06-23, 1391/04/03

Registrant information

Name

Masoud Etemadifar

Name of organization / entity

School of medicine, Isfahan University of Medical Sciences, Isfahan, Iran.

Country

Iran (Islamic Republic of)

Phone

+98 31166855552258

Email address

etemadifar.m@med.mui.ac.ir

Recruitment status

Recruitment complete

Funding source

Isfahan University of Medical Sciences

Expected recruitment start date

2010-04-21, 1389/02/01

Expected recruitment end date

2010-09-23, 1389/07/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of vitamin D3 supplementation in the prevention of Optic Neuritis conversion to Multiple Sclerosis in patients with low serum vitamin D status after one year follow up: a randomized double blind clinical trial.

Public title

The effect of vitamin D in Optic Neuritis outcome

Purpose

Prevention

Inclusion/Exclusion criteria

Entry criteria were as follows: (1) optic neuritis male or female patients with age range of 20-40 years, (2) patients should not fulfill the 2005 revised Mc Donald Criteria for multiple sclerosis, at the time of inclusion in the study,(3) serum 25(OH)D level of less than 30ng/ml (4) seronegativity for anti-aquaporin4 and other autoimmune antibodies, Exclusion criteria are:(1) patients who have used vitamin D supplements at a level higher than 400IU/day before the onset of optic neuritis,(2)patients who used any medication that could influence the prognosis of optic neuritis (e.g. β interferon) during the 12 months follow-up period,(3) women who were pregnant or breast feeding,(4) patients with kidney or liver dysfunction, (5)patients who demonstrated poor compliance with instructions to take vitamin D or placebo,or who failed to attend for follow-up visits, MRI scanning and vitamin D measurements during the study,(6)patients with a history of nephrolithiasis and(7) patients suffering from concurrent granulomatous diseases.

Age

From **20 years** old to **40 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **30**

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

The Local Ethics Committee of Medical Sciences in Isfahan

Street address

Isfahan University of Medical Sciences

City

Isfahan

Postal code

81745319

Approval date

2010-04-18, 1389/01/29

Ethics committee reference number

291041

Health conditions studied

1

Description of health condition studied

Optic neuritis

ICD-10 code

H46

ICD-10 code description

Optic neuritis

Primary outcomes

1

Description

The incidence rate of new demyelinating attack(s)

Timepoint

before and after the study

Method of measurement

complain(s) of patients, physical examination and MRI

Secondary outcomes

1

Description

The changes in MRI lesions

Timepoint

before and after study,during new attack(s)

Method of measurement

counting of MRI plaques

Intervention groups

1

Description

Administration of vitamin D3 at a dosage of 50000IU/week in the form of oral pearls to treatment group for 12 months.

Category

Treatment - Drugs

2

Description

Administration of a similar pearl shape placebo to control group for 12 months

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center
Isfahan Multiple Sclerosis Clinic
Full name of responsible person
Dr.Masoud Etemadifar
Street address
Alzahra Hospital of Isfahan
City
Isfahan

Etemadifar.M@med.mui.ac.ir ,
H.Derakhshandi84@yahoo.com
Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity
Medical school of Isfahan University of Medical Sciences
Full name of responsible person
Dr.Masoud Etemadifar
Position
Professor/MD
Other areas of specialty/work
Street address
Isfahan University of Medical Sciences
City
Isfahan
Postal code
Phone
+98 913 118 0249
Fax
Email
Etemadifar.M@med.mui.ac.ir
Web page address

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Isfahan University of Medical Sciences
Full name of responsible person
Dr. Ebrahim Esfandiari
Street address
Research and Technology Department of 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
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
Medical School of Isfahan University of Medical Sciences
Full name of responsible person
Hajar Derakhshandi
Position
Medical Student
Other areas of specialty/work
Street address
Isfahan University of Medical Sciences
City
Isfahan
Postal code
Phone
+98 913 271 6544
Fax
Email

Person responsible for updating data

Contact

Name of organization / entity
Medical School
Full name of responsible person
Hajar Derakhshandi
Position
Medical Student/ MD
Other areas of specialty/work
Street address
Isfahan University of Medical Sciences
City
Isfahan
Postal code
Phone
Fax
Email
Etemadifar.M@med.mui.ac.ir
H.Derakhshandi84@yahoo.com
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