Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

The effect of vitamin D3 supplemenation 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 20-40years) randomized clinical trial, 30 optic neuritis patients with serum 25(OH)D level of less than 30ng/ml who did not fulfill the 2005 Mc Donald Criteria for multiple sclerosis, were enrolled. The treatment group, received 50000IU/week of vitamin D3 and the control group received a placebo for 12months.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

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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 supplemenation 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 demyelinative 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
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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
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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
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

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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