Clinical Trial Protocol
Iranian Registry of Clinical Trials

01 Jun 2026

Effects of adjunct low-dose vitamin D on relapsing-remitting multiple sclerosis progression: Preliminary findings of a randomized, placebo-controlled trial

Protocol summary

Summary

The aim of this preliminary study is to evaluate the effect of low-dose oral vitamin D in combination with current disease modifying therapy on the prevention of progression of relapsing-remitting multiple sclerosis (RRMS). A phase II double-blind placebo-controlled randomized clinical trial will be conducted between October 200 and October 2011 included 50 patients with confirmed RRMS aged 25 to 57 years and normal serum 25-hydroxyvitamin D. The patients will be randomly allocated to receive 12-months of treatment with either escalating calcitriol doses up to 0.5 µg/day or placebo combined with disease-modifying therapy. Response to treatment will be assessed at eight week intervals. Primary and secondary outcome measures are number of relapse and changes in mean Expanded Disability Status Scale (EDSS).

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201104166202N1**
Registration date: **2011-04-29, 1390/02/09**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2011-04-29, 1390/02/09

Registrant information

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Mohsen Janghorbani
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Iran (Islamic Republic of)
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Recruitment status

Recruitment complete

Funding source

Isfahan University of Medical Sciences

Expected recruitment start date

2009-04-01, 1388/01/12

Expected recruitment end date

2011-06-01, 1390/03/11

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effects of adjunct low-dose vitamin D on relapsing-remitting multiple sclerosis progression: Preliminary findings of a randomized, placebo-controlled trial

Public title

Effects of adjunct low-dose vitamin D on relapsing-remitting multiple sclerosis progression: Preliminary findings of a randomized, placebo-controlled trial

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria: either sex, age between 15 and 60 years, diagnosis of definite RRMS with a MRI, clinical or laboratory, mean (standard deviation) duration equal to 4.3 (2.2) years, range 1-12 years, stable neurological functioning for at least one month prior to the study entry, EDSS score ≤6, serum 25-hydroxyvitamin D level>

40 ng/ml, willingness to continue current medications for the duration of the study Exclusion criteria: evidence of substantial abnormalities in neurological, psychiatric, cardiac, endocrinological, hematologic, hepatic, renal, or metabolic functions, use of digitalis, vitamin D supplement, any condition predisposing to hypercalcemia, nephrolithiasis, renal insufficiency, pregnancy as determined by history, physical examination and screening blood tests. secondary-progressive and primary-progressive MS, Women in child-bearing age with no clinically-accepted method of contraception

Age
From **15 years** old to **60 years** old

Gender
Both

Phase
2

Groups that have been masked
No information

Sample size
Target sample size: **50**

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
Isfahan University of Medical Sciences

Street address
School of Public Health, Isfahan University of Medical Sciences

City
Isfahan

Postal code
8144503500

Approval date
2008-06-07, 1387/03/18

Ethics committee reference number
386369

Health conditions studied

1

Description of health condition studied
relapsing-remitting multiple sclerosis

ICD-10 code
G35

ICD-10 code description
Multiple sclerosis

Primary outcomes

1

Description
Expanded Disability Status Scale (EDSS).

Timepoint
2-months interval, at the baseline and months 2, 4, 6, 8, 10 and 12

Method of measurement
Clinical evaluation by a qualified neurologist.

Secondary outcomes

1

Description
Number of relapses

Timepoint
2-months interval, at the baseline and months 2, 4, 6, 8, 10 and 12

Method of measurement
Clinical evaluation by a qualified neurologist.

Intervention groups

1

Description
Adjunct Calcitriol, (Trade name Zavitrol, Zahravi Pharm. Co. Tabriz, Iran), 0.25 µg per day (twice a day, orally before meals), increased to 0.5 µg/day after 2 weeks and will continue for 12- months as well as routine MS medications.

Category
Treatment - Drugs

2

Description
Placebo capsules, twice a day, orally before meals for 12-months as well as routine MS medications.

Category
Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center
Isfahan Neurosciences Research Center

Full name of responsible person

Mohsen Janghorbani and Vahid Shaygannejad

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School of Public Health, Isfahan University of Medical Sciences

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Isfahan

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Isfahan University of Medical Sciences

Full name of responsible person

Vahid Shatgannejad

Street address

Dept. of Neurology, Alzahrz Hospital

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

Isfahan University of Medical Sciences

Full name of responsible person

Mohsen Janghorbani

Position

Prof.

Other areas of specialty/work

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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