Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Study of Effects of Vitamin D on expression of TGF-βI, TGF-βII, TGF-β RI, TGF-β RII, NFκB1 and IL-10 genes in Multiple Sclerosis patient

Protocol summary

Summary

The goal of this study the effect of vitamin D on the expression TGF-βI, TGF-βII, TGF-β RI, TGF-β RII, NFκB1 and IL-10 genes in patients with multiple sclerosis will be reviewed. Therefore, 45 relapsing-remitting multiple sclerosis patients who have lower than normal levels of serum vitamin D (80NG/ML) are selected and their blood samples were taken and 50000IU of vitamin D per week for 8 weeks for they are prescribed. Eight weeks after patients received vitamin D blood sample is taken again. The expression of target genes at the level of mRNA extracted from the blood of patients before and after treatment will check Real Time PCR.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2014011216181N1**
Registration date: **2014-03-14, 1392/12/23**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2014-03-14, 1392/12/23

Registrant information

Name

Zeinab Shirvani Farsani

Name of organization / entity

Tarbiat Modares University

Country

Iran (Islamic Republic of)

Phone

+98 21 8288 4477

Email address

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Recruitment status

Recruitment complete

Funding source

Tarbiat Modares university of Tehran

Expected recruitment start date

2012-09-23, 1391/07/02

Expected recruitment end date

2013-09-24, 1392/07/02

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Study of Effects of Vitamin D on expression of TGF-βI, TGF-βII, TGF-β RI, TGF-β RII, NFκB1 and IL-10 genes in Multiple Sclerosis patient

Public title

Study of Effects of Vitamin D on expression of some of genes in MS patient

Purpose

Basic scienece

Inclusion/Exclusion criteria

Inclusion criteria: relapsing-remitting multiple sclerosis patients; MS patients with vitamin D deficiency (<80ng/ml). Exclusion criteria: patients treated with vitamin D supplements; progressive MS; relapsed patients.

Age

From **20 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)
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 Tarbiat Modares University

Street address
Nasr bridgs - Trabiat Modares University- School of Medicine

City
Tehran

Postal code

Approval date
2014-02-08, 1392/11/19

Ethics committee reference number
52/6723d

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
expression of IL10 gene

Timepoint
before vitamin D treatment and two month after treatment

Method of measurement
obtain of blood from patients and measurment of mRNA level

2

Description
expression of TGF-B1 gene

Timepoint
before vitamin D treatment and two month after treatment

Method of measurement
obtain of blood from patients and measurement of mRNA level

3

Description
expression of TGF-B2, TGF-B receptor I, TGFB receptor II, NF-KB, VDR gene

Timepoint
before vitamin D treatment and two month after treatment

Method of measurement
obtain of blood from patients and measurement of mRNA level

4

Description
serum vitamin D

Timepoint
before vitamin D treatment and two month after treatment

Method of measurement
obtain of blood from patients and measurement of serum vitamin D level

Secondary outcomes

empty

Intervention groups

1

Description
vitamin D, 50000 IU /a week , 8 weeks

Category
Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
MS Research Center

Full name of responsible person
Dr. Roozita Doosti

Street address

City
Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Tarbiat Modares University of Tehrean
Full name of responsible person
Dr. Mehrdad Behmanesh
Street address
Genetic Department,Faculty of Science, Tarbiat Modares University, Tehran, Iran
City
Tehran
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Tarbiat Modares University of Tehrean
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
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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