Clinical Trial Protocol
Iranian Registry of Clinical Trials

19 Nov 2026

The effect of vitamin D supplementation on the gene expression of interleukins 10, 17A and 6 in the apparently healthy first degree relatives of multiple sclerosis patients compared to apparently healthy people.

Protocol summary

Summary

The aim of this study is to investigate the effect of vitamin D supplementation on the Down/Up regulation of the components of See-Saw model in first degree relatives of Multiple sclerosis patients compared to the apparently healthy group. One of the study groups will consist of 23 first degree apparently healthy relatives of MS patients (such as son, daughter, sister and brother) and the other group is composed of 23 subjects who are free of any complication or genetic history (no history of MS in their relatives). The participants should fulfil inclusion criteria including age between 20-40 years old and being satisfied with blood sampling, and shouldn't have the exclusion criteria including malabsorption; consumption of medicine interacting with vitamin D; consuming vitamin D and Ca supplementation; pregnancy and lactation. The intervention in this study will be supplement therapy by vitamin D for 8 weeks, 50000 IU/week for both groups. Interleukins 6, 10 and 17A (levels of IL-6, IL-10, IL-17A) will be assessed in both groups as main outcomes.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201703033655N3**
Registration date: **2017-03-28, 1396/01/08**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2017-03-28, 1396/01/08

Registrant information

Name

Seyed Rafi Arefhosseini

Name of organization / entity

Tabriz University of Medical Sciences

Country

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Recruitment status

Recruitment complete

Funding source

1-Tabriz University of Medical Sciences2-Ardabil University of Medical Sciences

Expected recruitment start date

2017-02-19, 1395/12/01

Expected recruitment end date

2017-05-19, 1396/02/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of vitamin D supplementation on the gene expression of interleukins 10, 17A and 6 in the apparently healthy first degree relatives of multiple sclerosis patients compared to apparently healthy people.

Public title

The effect of vitamin D in the prevention of MS disease in first degree relatives of MS patients.

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria :the ability to give blood sample; tendency to take part in the study and filling FFQ and food record forms; having 20-40 years old. Exclusion criteria: having malabsorption; consumption of medicine that interact with Vitamin D absorption; catching chronic and immune system diseases; consumption of Ca & Vitamin D supplementation; pregnancy and lactation.

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

Gender
Both

Phase
3

Groups that have been masked
No information

Sample size
Target sample size: **46**

Randomization (investigator's opinion)
Not randomized

Randomization description

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics Committee of Tabriz University of Medical Sciences

Street address
Golgasht Ave

City
Tabriz

Postal code

Approval date
2016-10-18, 1395/07/27

Ethics committee reference number
IR.TBZMED.REC.1395.780

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
Interleukin 10

Timepoint
twice: before and after intervention (after 2 months)

Method of measurement
by Real Time-PCR

2

Description
Interleukin 17A

Timepoint
twice: before and after intervention (after 2 months)

Method of measurement
by Real Time-PCR

3

Description
Interleukin 6

Timepoint
twice: before and after intervention (after 2 months)

Method of measurement
by Real Time-PCR

4

Description
25- hydroxy vitamin D level

Timepoint
twice: before and after intervention (after 2 months)

Method of measurement
by Electro Chemiluminescence

Secondary outcomes

1

Description
creatinine serum

Timepoint
twice: before and after intervention (after 2 months)

Method of measurement
by Enzymatic Method

Intervention groups

1

Description
Control group: supplement therapy by vitamin D for 8 weeks, 50000 IU/week.

Category
Prevention

2

Description

Intervention group: supplement therapy by vitamin D for 8 weeks, 50000 IU/week.

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Genetic Lab, Ardabil University of Medical Sciences

Full name of responsible person

Dr.S Saied Hosseini-Asl

Street address

Daneshgah Ave

City

Ardabil

2

Recruitment center

Name of recruitment center

MS society of Ardabil province

Full name of responsible person

Sadegh Moharammzadeh

Street address

Sady St,

City

Ardabil

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research, Tabriz University of Medical Sciences

Full name of responsible person

Dr.Bahram Pourghassem

Street address

Golgasht Ave

City

Tabriz

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, Tabriz University of Medical Sciences

Proportion provided by this source

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

2

Sponsor

Name of organization / entity

Vice chancellor for research, Ardabil University of Medical Sciences

Full name of responsible person

Dr.Shahram Habibzadeh

Street address

Daneshgah Ave

City

Ardabil

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, Ardabil University of Medical Sciences

Proportion provided by this source

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

Faculty of Nutrition and Food Science, Tabriz University of Medical Sciences

Full name of responsible person

Dr.Syed Rafie Aref Hosseini

Position

PhD in nutrition biochemistry-Associate Professor

Other areas of specialty/work

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Person responsible for scientific inquiries

Contact

Name of organization / entity

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Person responsible for updating data

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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