Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

The effect of vitamin D supplementation on the gene expression of See-Saw model interleukins in the first degree of apparently healthy relatives of multiple sclerosis patients.

Protocol summary

Summary

The aim of this study were to investigate the effect of vitamin D supplementation on the down or upregulation of the components of See-Saw model, in first degree relatives of Multiple sclerosis patients, however it also compared to an apparently healthy group. Interleukins (levels of IL-10, IL-17A, IL-6) are assessed in the first degree of apparently healthy relatives of Multiple Sclerosis (MS) patients and compared with Blank group. The study group is controlled by vitamin D. The treatment groups will be include of 23 people of first degree apparently healthy relatives of MS patients first degree relatives such as (son, daughter, sister and brother) and blank groups would be consisted of 23 subjects free from any complication and genetic history (no history of MS in their relatives). These groups should have inclusion criteria, for instance, with ages between 20-40 years old, could donate blood samples, tend to take part in study and fill food frequency questionnaire (FFQ) and food record forms and should lack of exclusion criteria, malabsorption, consumption of medicine that interact with vitamin D, consumption vitamin D and Ca supplementation and gestation and lactation. In this interventional study that will be conducted in each group by a before and after design, any person that participate in this study will provide 10 ml blood samples at each stage . They also will provide serum samples for 25-hydroxy vitamin D by Electro Chemiluminescence (ECL) and the gene expression of See-Saw model's interleukins (IL-10, IL-17A, IL-6) by Real Time-PCR will be measured. Afterward, each group will intake vitamin D supplementation for 2 months (8 weeks) at a rate of 50000 IU per week. Besides more, food intake of vitamin D will be assessed by FFQ and food record in treatment, blank and Multiple sclerosis groups. the main objective of this study is assessment of the probable effects of vitamin D supplementation on Downregulation phenomenon by evaluating of gene expression for proinflamatory interleukins that have involved in MS disease and Upregulation phenomenon of gene expression for antiinflamatory interleukin that provide protective role in MS disease

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201008163655N2**
Registration date: **2016-11-06, 1395/08/16**
Registration timing: **prospective**

Last update:
Update count: **0**

Registration date

2016-11-06, 1395/08/16

Registrant information

Name

Seyed Rafi Arefhosseini

Name of organization / entity

Tabriz University of Medical Sciences

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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
2017-02-19, 1395/12/01
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 See-Saw model interleukins in the first degree of apparently healthy relatives of multiple sclerosis patients.

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 :could donate blood samples; tend to take part in study and fill FFQ and food record forms; having 20-40 years old. Exclusion criteria: having ma labsorption; consumption of medicine that interact with Vitamin D absorption; catching chronic and immune system diseases; consumption of Ca & Vitamin D supplementation; gestation and lactation.
Age
From **25 years** old to **35 years** old
Gender
Both

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **46**
Randomization (investigator's opinion)
Randomized
Randomization description
Blinding (investigator's opinion)
Single blinded
Blinding description
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
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 2 months
Method of measurement
by Real Time-PCR

2

Description
Interleukin 17A
Timepoint
twice : before and after 2 months
Method of measurement
by Real Time-PCR

3

Description
Interleukin 6
Timepoint
twice : before and after 2 months
Method of measurement
by Real Time-PCR

4

Description
25- hydroxy vitamin D level
Timepoint
twice : before and after 2 months
Method of measurement
by Electro Chemiluminescence

Secondary outcomes

1

Description
serum creatinine
Timepoint
twice : before and after 2 months
Method of measurement
by Enzymatic Method

2

Description
Weight
Timepoint
once : before intervention
Method of measurement
by digital scales with 0.1 Kg sensitivity

3

Description
Body Mass Index (BMI)
Timepoint
once : before intervention
Method of measurement
calculated with Quetlet's formula(weight(kg)/(height*height(m)))

Intervention groups

1

Description
treatment group : vitamin D supplementation, 50000 IU/week, for 8 weeks.
Category
Other

2

Description
control group : placebo of starch or Maltodextrose,for 8 weeks.
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Ardabil University of Medical Sciences
Full name of responsible person
Dr. Seyed Saied Hosseini-Asl
Street address
Daneshgah Ave,
City
Ardabil

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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
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
Ardabil University of Medical Sciences
Full name of responsible person
Dr.Shahram Habibzadeh
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Daneshgah Ave
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Ardabil
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
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
Tabriz University of Medical Sciences,Faculty of

Nutrition and Food Sciences

Full name of responsible person

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Position

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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