

Clinical Trial Protocol

Iranian Registry of Clinical Trials

09 Jun 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 proinflammatory interleukins that have involved in MS disease and Upregulation phenomenon of gene expression for antiinflammatory 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 malabsorption; consumption of medicine that interact with Vitamin D absorption; catching chronic and immune system diseases; consumption of Ca & Vitamin D supplementation; gestation and lactation.

AgeFrom **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($\text{weight(kg)} / (\text{height}^2(\text{m}))$)

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

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

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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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