Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Jul 2026

Treg/Th17 axis : the impact of vitamin D supplementation on TGF-β and IL-17A balance and mRNA expression in Multiple Sclerosis patients compared to apparently healthy first degree relatives of patients and apparently healthy people.

Protocol summary

Study aim

comparison of vitamin D supplementation on expression of IL-17A and TGF-B genes in multiple sclerosis (MS) patients, apparently healthy first degree relatives of patients and apparently healthy people.

Design

This study is controlled by vitamin D which intervention group will consist of 25 MS patints, while the control groups will include 25 apparently healthy first degree relatives of MS patients (such as son, daughter, sister and brother) and 25 apparently healthy subjects who are free of any complication or genetic history (no history of MS in their relatives). 25 people for each group out of all participants that will meet all inclusion criteria will randomize through simple random sampling. Allocating to each group will be through lottery and random paper which have been concealed in draw balls.

Settings and conduct

Whole blood samples (10 ml) will obtain from the participants before and after the trial and the serum levels of 25-(OH) vitamin D3 will measure using Electro Chemiluminescence (ECL) assay. Then, total RNA will extract and followed by total RNA, cDNA synthesis will do. Real-time PCR will perform using primers specific for TGF-B, IL-17A, along with β-actin as a housekeeping control.

Participants/Inclusion and exclusion criteria

Inclusion: 1.The ability to give blood sample; 2.Tendency to take part in the study; 3.having 20-40 years old; 4.Verifying MS diseases by a neurologist expert.
Exclusion: 1.Having malabsorption; 2.Consumption of medicine that interact with Vitamin D absorption; 3.Catching chronic and immune system diseases; 4.Consumption of Ca & Vitamin D supplementation; 5.pregnancy and lactation

Intervention groups

The intervention in this study will be administrated by vitamin D for 8 weeks, 50000 IU/week for three groups.

Main outcome variables

Interleukins 17A and TGF-B will be assessed in all of three groups as a main outcomes.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20100407003655N4**
Registration date: **2018-11-02, 1397/08/11**
Registration timing: **prospective**

Last update: **2018-11-02, 1397/08/11**
Update count: **0**

Registration date

2018-11-02, 1397/08/11

Registrant information

Name

Seyed Rafi Arefhosseini

Name of organization / entity

Tabriz University of Medical Sciences

Country

Iran (Islamic Republic of)

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+98 41 1444 4782

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-12-22, 1397/10/01

Expected recruitment end date

2019-06-21, 1398/03/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Treg/Th17 axis : the impact of vitamin D supplementation on TGF-β and IL-17A balance and mRNA expression in Multiple Sclerosis patients compared to apparently healthy first degree relatives of patients and apparently healthy people.

Public title

Affecting of vitamin D administration on mRNA expression of Treg/Th17 axis.

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria:

The ability to give blood sample Tendency to take part in the study having 20-40 years old Verifying MS diseases by a neurologist expert No receiving of vitamin D supplementation in the last 2 months

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: **75**

Randomization (investigator's opinion)

Randomized

Randomization description

Twenty-five people for each group out of all participants that will meet all inclusion criteria will randomize through simple random sampling. Allocating to each group will be through lottery and random paper which have been concealed in draw balls.

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Other

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

City

Tabriz

Province

East Azarbaijan

Postal code

5166614711

Approval date

2018-10-22, 1397/07/30

Ethics committee reference number

IR.TBZMED.REC.1397.608

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

IL-17A

Timepoint

Before and After supplementation

Method of measurement

Real time - PCR

2

Description

TGF-B

Timepoint

Before and After supplementation

Method of measurement

Real time - PCR

3

Description

Vitamin D

Timepoint

Before and After supplementation

Method of measurement
ECL

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group:
Category
Treatment - Other

2

Description
Control group:
Category
Treatment - Other

Recruitment centers

1

Recruitment center
Name of recruitment center
Tabriz University of Medical Sciences
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Sponsors / Funding sources

1

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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
100
Public or private sector
Public
Domestic or foreign origin
Domestic
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
Academic

Person responsible for general inquiries

Contact
Name of organization / entity
Tabriz University of Medical Sciences
Full name of responsible person
seyed Rafie Arefhosseini
Position
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available

Study Protocol
No - There is not a plan to make this available

Statistical Analysis Plan
No - There is not a plan to make this available

Informed Consent Form
Yes - There is a plan to make this available

Clinical Study Report
No - There is not a plan to make this available

Analytic Code
No - There is not a plan to make this available

Data Dictionary
No - There is not a plan to make this available

Title and more details about the data/document
only IPD collected for the primary outcome measure.

When the data will become available and for how long
after publication will start.

To whom data/document is available
available for people working in academic institutions

Under which criteria data/document could be used
this is not include especial criteria

From where data/document is obtainable
sending email to corresponding author

What processes are involved for a request to access data/document
after receiving email and coordinating with other colleagues, the demanded documents will be available.

Comments