Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

The effect of vitamin D Supplementation on the concentration & their gene expression & their transcription factors secreted by CD4 + T lymphocytes in hashimoto`s patients.

Protocol summary

Summary

1) Objectives, determine The effect of vitamin D Supplementation on the concentration & their gene expression & their transcription factors secreted by CD4 + T lymphocytes in hashimoto`s patients. 2) Design, this study is designed in the form of double blind clinical trial 3) setting & conduct, in this study 46 Woman refer to clinic are randomly divided in two groups , intervention group receive 50,000 IU vitamin D weekly for three months & control group receive placebo, from participants are being collected about 10 to 15 ml blood before & after supplementation & we measure anti TPO, anti Thyroglobulin ,vitamin D, T3, T4, TSH. We assess cytokines(IL4, INF Gama, TGF Beta, IL17)& transcription factors (T-bet,ROR-gt,FOXP3,GATA3) of immune system.anthropometric factors Dietary intake and sun exposure are also determined. 4) Participant, including female age between 20-50 with BMI between18.5-35 & they mustn't use vitamin D on three months ago. 5) Intervention, high-dose vitamin D supplementation on hashimoto disease (auto immune hypo thyroidits) intervention group receive 50,000 IU vitamin D weekly for three months & control group receive placebo, from participants were collected about 10 to 15 ml blood before & after supplementation. 6) main outcome measures, we will measure anti TPO, anti Thyroglobulin ,vitamin D, T3, T4, TSH. We will assess cytokines(IL4, INF Gama, TGF Beta, IL17)& transcription factors (T-bet,ROR-gt,FOXP3,GATA3) of immune system. Anthropometric factors Dietary intake and sun exposure will be determined.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016110130644N1**

Registration date: **2016-12-17, 1395/09/27**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2016-12-17, 1395/09/27

Registrant information

Name

Reza Chahardoli

Name of organization / entity

Cellular & molecular department of nutrition & dietetics of Tehran medical science

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

This study is supported by Shahid Behshti University of Medical Science & Mazandaran University of Medical Science about 40% & rest of that from Tehran University of Medical Science in the form of collaborative project.

Expected recruitment start date

2016-09-22, 1395/07/01

Expected recruitment end date

2016-12-21, 1395/10/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title
The effect of vitamin D Supplementation on the concentration & their gene expression & their transcription factors secreted by CD4 + T lymphocytes in hashimoto`s patients.

Public title
The effect of vitamin D in autoimmune hypothyroid patients.
Purpose
Treatment
Inclusion/Exclusion criteria
inclusion criteria included woman age between 20-50 years & willingness to participate in study;.the exclusion criteria woman suffering from malnutrition & obesity;woman with (BMI) <18 kg/m2 or (BMI) >35 kg/m2; being menopausal, pregnant or lactating; woman consumed vitamin D, vitamin A or omega-3 supplements with in the past 3 months; in take of use of medications that affect the metabolism of vitamin D and any preexisting specified disease that effect on th1/th2 balance like type 1 diabetes,Rheumatoid Arthritis,sarcoidosis,lupus& IBD ; have serious disease in hepatic, pancreas& biliary;alcoholic participant .
Age
From **20 years** old to **50 years** old
Gender
Female

Phase
2
Groups that have been masked
No information
Sample size
Target sample size: **38**
Randomization (investigator's opinion)
Randomized
Randomization description
Blinding (investigator's opinion)
Double blinded
Blinding description
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethical Committee of Tehran university of Medical Science
Street address
No.1 – Poursina St., Quds St.., Keshavarz Boulevard, Tehran , Iran
City
Tehran
Postal code
1417653861
Approval date
2016-10-16, 1395/07/25
Ethics committee reference number
IR.TUMS.VCR.REC.1395.783

Health conditions studied

1

Description of health condition studied
Hashimoto thyroiditis
ICD-10 code
E06.3
ICD-10 code description
Hashimoto thyroiditis Hashitoxicosis (transient) Lymphadenoid goitre Lymphocytic thyroiditis Struma lymphomatosa

Primary outcomes

1

Description
serum level of IL4
Timepoint
before & after intervetion
Method of measurement
ELISA

2

Description
serum level of IFN gama
Timepoint
before & after intervetion
Method of measurement
ELISA

3

Description
serum level of IL17
Timepoint
before & after intervetion
Method of measurement
ELISA

4

Description
serum level of TGF beta
Timepoint
before & after intervetion
Method of measurement
ELISA

5

Description

gene expression of IL-4
Timepoint
before & after intervetion
Method of measurement
real time PCR

6

Description
gene expression of IL-17
Timepoint
before & after intervetion
Method of measurement
real time PCR

7

Description
gene expression of TGF beta
Timepoint
before & after intervetion
Method of measurement
real time PCR

8

Description
gene expression of IFN gama
Timepoint
before & after intervetion
Method of measurement
real time PCR

9

Description
gene expression of T-bet
Timepoint
before & after intervetion
Method of measurement
real time PCR

10

Description
gene expression of ROR-gt
Timepoint
before & after intervetion
Method of measurement
real time PCR

11

Description
gene expression of Foxp3
Timepoint
before & after intervetion
Method of measurement
real time PCR

12

Description
gene expression of GATA3
Timepoint
before & after intervetion
Method of measurement
real time PCR

13

Description
serum level of anti TPO
Timepoint
before & after intervetion
Method of measurement
ELISA

14

Description
serum level of vit D
Timepoint
before & after intervetion
Method of measurement
ELISA

15

Description
serum level of T3
Timepoint
before & after intervetion
Method of measurement
ELISA

16

Description
serum level of T4
Timepoint
before & after intervetion
Method of measurement
ELISA

17

Description
serum level of ca
Timepoint
before & after intervetion
Method of measurement
colorimetry

Secondary outcomes

1

Description
weight
Timepoint
before & after intervention
Method of measurement
balance

2

Description
height
Timepoint
before & after intervention
Method of measurement
tape measure

3

Description
BMI
Timepoint
before & after intervention
Method of measurement
matematical measurment weight divided by the square of height

4

Description
waist circumference
Timepoint
before & after intervention
Method of measurement
tape measurment

Intervention groups

1

Description
the placebo pearls were put in similar plastic bottles are taken every week for 3 month by participant.
Category
Placebo

2

Description
the vitamin D pearls in 50, 000 IU were put in similar plastic bottles are taken every week for 3 month by participant.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Erfan hospital
Full name of responsible person
Dr Amozegar
Street address
Erfan hospital-sadat- abad Tehran Iran
City
Tehran

2

Recruitment center
Name of recruitment center
Endocrine center of Emamkhomini hospital
Full name of responsible person
Dr Hematabadi
Street address
chamran high way Tohid square emamkhomini hospital
City
Tehran

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
The SBMU Endocrine Research Center
Full name of responsible person
Dr fereydon Azizi
Street address
Araabi St., Yaman Ave, Chamran High Way, 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
The SBMU Endocrine Research Center
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
health faculty of Tehran University of Medical Sciences
Full name of responsible person
Dr Ali akbar saboor Yraghi
Street address
Immunology department health faculty of Tehran University of Medical Sciences– Poursina St., Quds St.., Keshavarz Boulevard, 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

health faculty of Tehran 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

Tehran university of medical science

Full name of responsible person

Reza Chahardoli

Position

PHD student

Other areas of specialty/work

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Immunology department health faculty of Tehran university of medical scince

Full name of responsible person

Dr. Ali Akbar Saboori-Yaraghi

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Associate Professor

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Person responsible for updating data

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Full name of responsible person

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Email

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Web page address

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