

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 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 thyroiditis) 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)

Phone

+98 21 4293 3168

Email address

chahardoli80@yahoo.com

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 intervention

Method of measurement

ELISA

2

Description

serum level of IFN gama

Timepoint

before & after intervention

Method of measurement

ELISA

3

Description

serum level of IL17

Timepoint

before & after intervention

Method of measurement

ELISA

4

Description

serum level of TGF beta

Timepoint

before & after intervention

Method of measurement

ELISA

5

Description

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

6

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

7

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

8

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

9

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

10

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

11

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

12

Description
gene expression of GATA3

Timepoint
before & after intervention
Method of measurement
real time PCR

13

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

14

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

15

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

16

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

17

Description
serum level of ca
Timepoint
before & after intervention
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

mathematical measurement weight divided by the square of height

4

Description

waist circumference

Timepoint

before & after intervention

Method of measurement

tape measurement

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**Street address**

Health faculty of tehran university of medical science-
Poursina St., Quds St., Keshavarz Boulevard, Tehran ,
Iran

City

Tehran

Postal code**Phone**

+98 21 4293 3036

Fax**Email**

chahardoli80@yahoo.com

Web page address**Person responsible for scientific inquiries****Contact****Name of organization / entity**

Immunology department health faculty of Tehran
university of medical science

Full name of responsible person

Dr. Ali Akbar Saboori-Yaraghi

Position

Associate Professor

Other areas of specialty/work**Street address**

Immunology department health faculty of Tehran
university of medical science- Poursina St., Quds St.,

Keshavarz Boulevard, Tehran , Iran

City

Tehran

Postal code**Phone**

0042933168

Fax**Email**

asaboor@sina.tums.ac.ir

Web page address**Person responsible for updating data****Contact****Name of organization / entity**

Cellular & molecular department of nutrition &
dietetics faculty of Tehran university of medical sci

Full name of responsible person

Reza Chahardoli

Position

PHD student

Other areas of specialty/work**Street address**

Health faculty of Tehran university of medical
science- Poursina St., Quds St., Keshavarz Boulevard,
Tehran , Iran

City

Tehran

Postal code**Phone**

+98 21 4293 3036

Fax

+98 21 4293 3035

Email

Chahardoli80@yahoo.com

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