

Clinical Trial Protocol

Iranian Registry of Clinical Trials

28 May 2026

The effect of vitamin D intake on AntiTPO levels in hypothyroid and euthyroid patients with anti-TPO positive: an interventional study

Protocol summary

Study aim

Evaluation of the effect of vitamin D intake on AntiTPO levels in hypothyroid and euthyroid patients with anti-TPO positive.

Design

Interventional clinical trial without a control group, with parallel groups, non-random, without blinding on 128 patients

Settings and conduct

An intervention study in which patients with AntiTPO positive and vitamin D deficiency receive vitamin D supplementation and serum AntiTPO levels of patients are measured 3and6 months later. Patients referred to thelaboratory are included in the study through

Participants/Inclusion and exclusion criteria

Inclusion criteria: Patients of both sexes who have AntiTPO positive and their disease is approved by an endocrinologist and are in the age range of 18 to 65 years. no entry criteria: Patients who have evidence of any disease that affects the immune system balance, such as those with type 1 diabetes, multiple sclerosis, inflammatory bowel disease, and other autoimmune diseases. Those with impaired liver enzymes There are patients with malnutrition, patients with a BMI of less than 18 or more than 40. Patients with hyperthyroidism and a decrease in TSH.

Intervention groups

Intervention group1: Patients who are Anti-TPO positive and have elevated TSH and are deficient in vitamin D whose serum level of vitamin D is less than 10ng /ml.
Intervention group2: Patients who are anti-TPO positive and have elevated TSH and insufficient vitamin D with serum levels of vitamin D between 10ng/ml to 20ng/ml.
Intervention group3: Patients who are anti-TPO positive and have normal TSH and are deficient in vitamin D whose serum level of vitamin D is less than 10ng/ml.
Intervention group4: Patients who are anti-TPO positive and have normal TSH and insufficient vitamin D with serum levels of vitamin D between 10ng/ml to 20ng/ml.

Main outcome variables

Serum levels of Anti TPO before and after taking vitamin D.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20210802052054N1**

Registration date: **2022-05-14, 1401/02/24**

Registration timing: **registered_while_recruiting**

Last update: **2022-05-14, 1401/02/24**

Update count: **0**

Registration date

2022-05-14, 1401/02/24

Registrant information

Name

Sima Shahmohammadi-farid

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 41 3334 3888

Email address

shahmohammadis@tbzmed.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-05-14, 1401/02/24

Expected recruitment end date

2022-11-15, 1401/08/24

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date
empty

Scientific title
The effect of vitamin D intake on AntiTPO levels in hypothyroid and euthyroid patients with anti-TPO positive: an interventional study

Public title
Evaluation of the effect of vitamin D consumption on the AntiTPO

Purpose
Supportive

Inclusion/Exclusion criteria
Inclusion criteria:
Patients of both sexes who have AntiTPO positive and their disease is approved by an endocrinologist and are in the age range of 18 to 65 years.
Exclusion criteria:
Patients who have evidence of any disease that affects the balance of the immune system, such as those with type 1 diabetes, multiple sclerosis, inflammatory bowel disease, and other autoimmune diseases. Patients with impaired liver enzyme function Malnourished patients Patients with a BMI of less than 18 or more than 40. Patients with hyperthyroidism and decreased TSH levels.

Age
From **18 years** old to **65 years** old

Gender
Both

Phase
2

Groups that have been masked
No information

Sample size
Target sample size: **128**

Randomization (investigator's opinion)
N/A

Randomization description

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Not used

Assignment
Parallel

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

Central Office of Tabriz University of Medical Sciences
Tabriz -Golghasht St.- Azadi St.

City

Tabriz

Province

East Azarbaijan

Postal code

5166614766

Approval date

2021-09-13, 1400/06/22

Ethics committee reference number

IR.TBZMED.REC.1400.568

Health conditions studied

1

Description of health condition studied

Autoimmune Hypothyroidism

ICD-10 code

E06.3

ICD-10 code description

Autoimmune thyroiditis

Primary outcomes

1

Description

Serum levels of Anti TPO before and after taking vitamin D.

Timepoint

Anti TPO levels are measured before the intervention and 3 and 6 months after the start of vitamin D intake.

Method of measurement

After starting the study, blood samples are taken from the patients and the patients' serum is removed. Using special Anti TPO kits, the level of Anti TPO is measured by ELISA and the effect of vitamin D level on the level of Anti TPO in the serum is examined.

Secondary outcomes

1

Description

Evaluation of serum vitamin D levels in patients with Anti TPO positive

Timepoint

Serum vitamin D levels are measured before the intervention and 3 and 6 months after the start of vitamin D intake

Method of measurement

After starting the study, blood samples are taken from the patients and the patients' serum is removed. Using special Vitamin D kits, the level of vitamin D is measured by ELISA.

Intervention groups

1

Description

Intervention group: Patients who are Anti-TPO positive and have elevated TSH and are deficient in vitamin D whose serum level of vitamin D is less than 10ng /ml . For 8 weeks, 50,000 units of vitamin D3 tablets will be prescribed every week. After 8 weeks, 800 to 1000 units of vitamin D will be prescribed daily.

Category

Treatment - Drugs

2

Description

Intervention group: Patients who are anti-TPO positive and have elevated TSH and insufficient vitamin D with serum levels of vitamin D between 10ng/ml to 20ng/ml. 800 to 1000 units of vitamin D are prescribed daily for 3 months.

Category

Treatment - Drugs

3

Description

Intervention group: Patients who are anti-TPO positive and have normal TSH and are deficient in vitamin D whose serum level of vitamin D is less than 10ng/ml. For 8 weeks, 50,000 units of vitamin D3 tablets will be prescribed every week. After 8 weeks, 800 to 1000 units of vitamin D will be prescribed daily.

Category

Treatment - Drugs

4

Description

Intervention group: Patients who are anti-TPO positive and have normal TSH and insufficient vitamin D with serum levels of vitamin D between 10ng/ml to 20ng/ml. 800 to 1000 units of vitamin D are prescribed daily for 3 months.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Sadr Laboratory

Full name of responsible person

Sima shahmohammadi Farid

Street address

Tabriz, Vala Asr uphill

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tabriz University of Medical Sciences

Full name of responsible person

Mohammad Samiei

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reasearch-vice@tbzmed.ac.ir

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

Sima Shahmohammadi Farid

Position

assistant professor

Latest degree

Ph.D.

Other areas of specialty/work

Immunology

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

Tabriz University of Medical Sciences

Full name of responsible person

Sima Shahmohammadi Farid

Position

Asistant Professor

Latest degree

Ph.D.

Other areas of specialty/work

Immunology

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

Tabriz University of Medical Sciences

Full name of responsible person

Ali Yousefipour

Position

medical student

Latest degree

Medical doctor

Other areas of specialty/work

General Practitioner

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Sharing plan**Deidentified Individual Participant Data Set (IPD)**

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

Not applicable

Analytic Code

Not applicable

Data Dictionary

Not applicable

Title and more details about the data/document

A portion of the data will be shared.

When the data will become available and for how long

2023-2024

To whom data/document is available

Researchers and academic staffs

Under which criteria data/document could be used

For further studies

From where data/document is obtainable

Request via email:ali_you_2015@yahoo.co.uk

What processes are involved for a request to access data/document

Request via email :ali_you_2015@yahoo.co.uk

Comments