

# 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 the ....laboratory 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

#### City

Tabriz

#### Province

East Azarbaijan

#### Postal code

5166/15731

#### Phone

+98 41 1334 3010

#### Email

shahmohammadis@tbzmed.ac.ir

## Sponsors / Funding sources

## 1

### Sponsor

#### Name of organization / entity

Tabriz University of Medical Sciences

#### Full name of responsible person

Mohammad Samiei

#### Street address

Golgasht Street

#### City

Tabriz

#### Province

East Azarbaijan

#### Postal code

5166/15731

#### Phone

+98 41 5333 0896

#### Email

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

#### Street address

Golgasht Street

#### City

Tabriz

**Province**

East Azarbaijan

**Postal code**

5166/15731

**Phone**

+98 41 1334 3010

**Email**

shahmohammadis@tbzmed.ac.ir

**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

**Street address**

Golgasht Street

**City**

Tabriz

**Province**

East Azarbaijan

**Postal code**

5166/15731

**Phone**

+98 41 1334 3010

**Email**

shahmohammadis@tbzmed.ac.ir

**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

**Street address**

No1026,East Second floor, Azarabadegan Ave, Third daneshgah Ave, Nasr Town

**City**

Tabriz

**Province**

East Azarbaijan

**Postal code**

5158375751

**Phone**

+98 41 3662 8155

**Email**

ali\_you\_2015@yahoo.co.uk

**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**