

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

17 Sep 2026

### Effects of treatment with vitamin D3 in Hashimoto's Thyroiditis with vitamin D deficiency on Thyroid function, antithyroid antibodies and metabolic markers

#### Protocol summary

##### Summary

**Objective:** The aim of this study is to evaluate the effects of treatment with vitamin D on thyroid function, metabolic markers and antithyroid antibodies in Hashimoto's thyroiditis patients with low serum vitamin D level. **Design:** This study is randomized double-blind placebo-Controlled trial **Setting and conduct:** The trial is undertaken in Isfahan endocrinology and metabolism research center. About 60 anti TPO positive euthyroid or hypothyroid persons with serum vitamin D level lower than 20 ng/ml are randomly assigned to receive vitamin D or placebo weekly for 12 weeks. **Inclusion and exclusion criteria:** All patients are between 20 to 60 year-old; anti TPO positive with vitamin D level lower than 20ng/ml; euthyroid or hypothyroid and more than six months using current prescriptions. We exclude patients who receive Insulin or immunosuppressive drugs or dietary supplementations; confounding comorbid disease and severe weight loss. **Intervention:** Blood samples will be obtained before trial and controls will receive placebo weekly for 12 weeks and target group will receive vitamin D 50000 unit weekly for 12 weeks.at the end second blood sample will be obtained. **Main outcome measurements:** Anti TPO (anti tissue peroxidase);TSH (thyroid stimulating hormone );fasting blood glucose; lipid profiles; calcium; phosphorus; albumin ;parathormone (PTH) ;urea ; creatinine and insulin are measured at the beginning and the end independent pair T test is used for between and within group analysis respectively .

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT2014120520216N1**  
Registration date: **2015-12-02, 1394/09/11**

Registration timing: **retrospective**

Last update:

Update count: **0**

##### Registration date

2015-12-02, 1394/09/11

##### Registrant information

###### Name

Parichehr Vahabi Anaraki

###### Name of organization / entity

Isfahan University of Medical Science; Department of Endocrinology

###### Country

Iran (Islamic Republic of)

###### Phone

+98 31 3669 7913

###### Email address

pari.vahabi@med.mui.ac.ir

##### Recruitment status

###### Recruitment complete

##### Funding source

Endocrinology Research Center, Isfahan University of Medical Science; Zahravy Pharmaceutical Company

##### Expected recruitment start date

2014-12-22, 1393/10/01

##### Expected recruitment end date

2015-03-20, 1393/12/29

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Effects of treatment with vitamin D3 in Hashimoto's

Thyroiditis with vitamin D deficiency on Thyroid function, antithyroid antibodies and metabolic markers

**Public title**  
Effects of treatment with vitamin D3 in Hashimoto's Thyroiditis with vitamin D deficiency on Thyroid function, antithyroid antibodies and metabolic markers

**Purpose**  
Treatment

**Inclusion/Exclusion criteria**  
Inclusion criteria: age 20 to 60 years; anti thyroid peroxidase antibody positive; serum 25 hydroxyl vitamin D 3 is less than 20 nanogram per milliliter; euthyroid or hypothyroid; if Levothyroxin or other metabolic drugs like Statins, Metformin consumed, starting time was more than 6 months ago. Exclusion criteria: immunosuppressor drugs intake before the study; dietary supplementation intake per oral or injections before study; comorbid disease ; severe weight loss; insulin taking.

**Age**  
From **20 years** old to **60 years** old

**Gender**  
Both

**Phase**  
2-3

**Groups that have been masked**  
*No information*

**Sample size**  
Target sample size: **60**

**Randomization (investigator's opinion)**  
Randomized

**Randomization description**

**Blinding (investigator's opinion)**  
Double blinded

**Blinding description**

**Placebo**  
Used

**Assignment**  
Parallel

**Other design features**  
The patient determines her or his group by drawing one closed envelope

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Ethics Committee, Isfahan University of Medical Science

##### Street address

Central Organization, Isfahan University of Medical Science, Hezar Jerib Boulevard

##### City

Isfahan

##### Postal code

#### Approval date

2014-09-23, 1393/07/01

#### Ethics committee reference number

394105

## Health conditions studied

### 1

#### Description of health condition studied

Hashimoto's thyroiditis

#### ICD-10 code

E06.3

#### ICD-10 code description

Autoimmune thyroiditis: Hashimoto's thyroiditis, Temporary hashitoxicosis, Lymphadenoid thyroiditis, Lymphocytic thyroiditis, Lymphomatosis Stroma

## Primary outcomes

### 1

#### Description

25, hydroxyl vitamin D3

#### Timepoint

before entering to the study & 12 weeks after drug or placebo consumption

#### Method of measurement

serum level measurement

### 2

#### Description

TPOAb

#### Timepoint

before entering to the study & 12 weeks after drug or placebo consumption

#### Method of measurement

serum level measurement

### 3

#### Description

Thyroid Stimulating Hormone (TSH)

#### Timepoint

before entering to the study & 12 weeks after drug or placebo consumption

#### Method of measurement

serum level measurement

## Secondary outcomes

### 1

#### Description

Calcium

#### Timepoint

before entering to the study & 12 weeks after drug or placebo consumption

#### Method of measurement

serum level measurement

## 2

### Description

PTH

### Timepoint

before entering to the study & 12 weeks after drug or placebo consumption

### Method of measurement

serum level measurement

## Intervention groups

### 1

#### Description

intervention group 1: 50.000 units of Vitamin D prescription weekly and per oral for 12 weeks

#### Category

Treatment - Drugs

### 2

#### Description

control group: placebo prescription weekly per oral for 12 weeks

#### Category

Placebo

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Endocrinology research center; Sedigheh Tahereh Hospital

##### Full name of responsible person

Dr Parichehr Vahabi Anaraki

##### Street address

Khorram Street

##### City

Isfahan

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Vice Chancellor for research, Isfahan University of Medical Science

##### Full name of responsible person

Dr Mehdy Nematbakhsh

##### Street address

Vice Chancellor for research, No 4 Building, Isfahan University of Medical Science, Hezarjerib Street

##### City

Isfahan

##### Grant name

##### Grant code / Reference number

##### Is the source of funding the same sponsor organization/entity?

Yes

#### Title of funding source

Vice Chancellor for research, Isfahan University of Medical Science

#### 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

Zahravi Pharmaceutical Company

##### Full name of responsible person

Dr Majeed Annabi

##### Street address

No 178, West Hoveyze St., Saboonchi St., Shahid Beheshti St.

##### City

Tehran

##### Grant name

##### Grant code / Reference number

##### Is the source of funding the same sponsor organization/entity?

Yes

#### Title of funding source

Zahravi Pharmaceutical Company

#### 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

Isfahan University of Medical Science

##### Full name of responsible person

Dr Parichehr Vahabi Anaraki

##### Position

Endocrinology assistant

##### Other areas of specialty/work

##### Street address

Endocrinology Department, Alzahra Hospital

##### City

Isfahan

##### Postal code

##### Phone

+98 31 3669 7913

**Fax**  
**Email**  
pari.vahabi@med.mui.ac.ir  
**Web page address**

## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**  
Isfahan University of Medical Science, Endocrinology Department  
**Full name of responsible person**  
Dr Ashraf Aminorroaya  
**Position**  
MD, Endocrinologist  
**Other areas of specialty/work**  
**Street address**  
Endocrinology Department, Alzahra Hospital  
**City**  
Isfahan  
**Postal code**  
**Phone**  
+98 31 3441 1601  
**Fax**  
+98 31 3344 2908  
**Email**  
aminorroaya@med.mui.ac.ir  
**Web page address**

## Person responsible for updating data

### Contact

**Name of organization / entity**

Isfahan University of Medical Science  
**Full name of responsible person**  
Dr Parichehr Vahabi Anaraki  
**Position**  
Endocrinology assistant  
**Other areas of specialty/work**  
**Street address**  
Endocrinology Department, Alzahra Hospital  
**City**  
Isfahan  
**Postal code**  
8168835443  
**Phone**  
+98 31 3669 7913  
**Fax**  
**Email**  
pari.vahabi@med.mui.ac.ir  
**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*