

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)

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+98 31 3669 7913

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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

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Person responsible for scientific inquiries

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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