

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Jun 2026

Impact of vitamin D treatment on TSH level, in subclinical hypothyroidism & vitamin D deficient women

Protocol summary

Summary

This study aims to investigate the effect of vitamin D treatment on TSH level in the women suffering from subclinical hypothyroidism and vitamin D deficiency. The criterion to be included in this research study was the women over 18 years affected with subclinical hypothyroidism (TSH level more than 5 and less than 10) and vitamin D deficiency (25 OHD3 less than 30), and that of exclusion from this study was the patients with systemic diseases (renal, liver or lung) and patients with chronic consumption of medication, which affect the metabolism of vitamin D, age over 65 and less than 18 years old. The population of the present study is female patients with subclinical hypothyroidism, of which a sample 25 female patients afflicted with subclinical hypothyroidism and have referred to Endocrinology Clinic in Imam Reza Tabriz Hospital or medical offices of Endocrinologists in Tabriz, were randomly chosen for this study taking into consideration the criterion of inclusion and exclusion from this research study. The intervention devised to prescribe the vitamin D to the qualified patients and investigation of its effect on the level of thyroid stimulating hormone 3 months later was a primary consequence. The time of intervention was estimated 6 months later.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016062813612N8**

Registration date: **2016-09-02, 1395/06/12**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2016-09-02, 1395/06/12

Registrant information

Name

Farzad Najafipour

Name of organization / entity

Tabriz University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 41 1335 7850

Email address

najafipourf@tbzmed.ac.ir

Recruitment status

Recruitment complete

Funding source

Vice Chancellor for Research of Tabriz University of Medical Sciences

Expected recruitment start date

2016-08-05, 1395/05/15

Expected recruitment end date

2017-08-22, 1396/05/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Impact of vitamin D treatment on TSH level, in subclinical hypothyroidism & vitamin D deficient women

Public title

Effect of vitamin D treatment on TSH level, in subclinical hypothyroidism & vitamin D deficient women

Purpose

Treatment

Inclusion/Exclusion criteria

Criteria for this study: women over 18 years old; patients with subclinical hypothyroidism with TSH higher than 4.5 mlu / L and less than 10 mlu / L; patients with vitamin D

deficiency who are defined with 25 (OH) D3 less than 30 mlu / L. Exclusion criteria: patients with systemic diseases (Kidney - lung - Haematic - Digestive); taking medicatiobs that affect on the metabolism of vitamin D; older than 65 years old or younger than 18 years old; being pregnant or plan to become pregnant; patient dissatisfaction to participate in the study.

Age

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

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **25**

Randomization (investigator's opinion)

N/A

Randomization description**Blinding (investigator's opinion)**

Not blinded

Blinding description**Placebo**

Not used

Assignment

Single

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

Ethics Committee, Tabriz University of Medical Sciences, Golgasht Street , Tabriz

City

Tabriz

Postal code**Approval date**

2016-08-03, 1395/05/13

Ethics committee reference number

IR.TBZMED.REC.1395.416

Health conditions studied**1****Description of health condition studied**

Subclinical hypothyroidism

ICD-10 code

E01.2

ICD-10 code description

Iodine-deficiency-related (endemic) goitre, unspecified

Primary outcomes**1****Description**

Thyroid-stimulating hormone(TSH)

Timepoint

Baseline and 3 months after treatment

Method of measurement

Test

2**Description**

Vitamin D

Timepoint

Baseline and 3 months after treatment

Method of measurement

Test

Secondary outcomes**1****Description**

Thyroid Function (FT4)

Timepoint

Baseline and 3 months after treatment

Method of measurement

Test

2**Description**

Thyroid peroxidase antibody

Timepoint

Baseline and 3 months after treatment

Method of measurement

Test

Intervention groups**1****Description**

For patients, vitamin D (50,000 IU capsule per week for 8 weeks) is recommended.

Category

Treatment - Drugs

Recruitment centers**1****Recruitment center****Name of recruitment center**

Tabriz, Imam Reza Hospital

Full name of responsible person

Dr. Kiarash Aminian

Street address

Department of Endocrinology, Imam Reza Hospital,
Gate University, Tabriz, East Azarbaijan

City

Tabriz

Email

farzad278@yahoo.com

Web page address**Sponsors / Funding sources****1****Sponsor****Name of organization / entity**

Vice Chancellor for Research of Tabriz University of
Medical Sciences

Full name of responsible person

Dr. Mohammad Reza Rashidi

Street address

Vice chancellor for Research of Tabriz University of
Medical Sciences, Tabriz University of Medical
Sciences, Golgasht Street, Tabriz

City

Tabriz

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 of Tabriz University of
Medical Sciences

Proportion provided by this source

100

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**

Tabriz University of Medical Sciences

Full name of responsible person

Dr. Farzad Najafipour

Position

Endocrinology and Metabolism/ Associate Professor

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

Department of Endocrinology, Imam Reza Hospital,
Tabriz University of Medical Sciences, Golgasht
Street, Tabriz

City

Tabriz

Postal code**Phone**

+98 41 3335 7850

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

Tabriz University of Medical Sciences

Full name of responsible person

Dr. Farzad Najafipour

Position

Endocrinology and Metabolism/ Associate Professor

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

Department of Endocrinology, Imam Reza Hospital,
Tabriz University of Medical Sciences, Golgasht
Street, Tabriz

City

Tabriz

Postal code**Phone**

+98 41 3335 7850

Fax**Email**

farzad278@yahoo.com

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

Tabriz University of Medical Sciences

Full name of responsible person

Dr. Kiarash Aminian

Position

Endocrinology and Metabolism Fellow

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

Department of Endocrinology, Imam Reza Hospital,
Gate University, Tabriz, East Azarbaijan

City

Tabriz

Postal code**Phone**

+98 41 3335 7850

Fax**Email**

kiarashamin@gmail.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