Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 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

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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

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

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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