Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

Effect of vitamin D supplementation on metabolic status, thyroid hormones, serum irisin and obesity indices in women with subclinical hypothyroidism

Protocol summary

Study aim
Effect of vitamin D supplementation on metabolic status, thyroid hormones, serum irisin and obesity indices in women with subclinical hypothyroidism

Design
A randomized, double-blind, placebo-controlled trial

Settings and conduct
44 patients with subclinical hypothyroidism will be randomly divided into two groups: the group receiving vitamin D (one perl 50,000 units per week) and the group receiving placebo (one perl containing sunflower oil similar to vitamin D). The patients will be selected from the endocrinology clinic of Imam Reza Hospital in Tabriz.

Participants/Inclusion and exclusion criteria
A total of 44 patients with hypothyroidism will be selected based on the inclusion criteria and informed written consent will be obtained from all participants before enrollment. Inclusion criteria: willingness to participate in the study, women aged 20 to 65 years with hypothyroidism, BMI25-37 Kg / m2, laboratory TSH between 5-10 micro units per ml and normal T3 and T4, test Anti-TPO positive; Exclusion criteria: unwillingness to participate in the study; Serum vitamin D level higher than 100 micrograms per liter; Smoking and alcohol; Pregnancy and lactation; Diabetes and infectious heart disease; Renal failure; Cushing's syndrome; Liver disease; Use of drugs that affect the level of thyroid hormones including lithium, amiodarone, steroids, hypolipidemic drugs, antidepressants, oral contraceptives; Regular consumption of any dietary supplement during the last 2 months and during the study; Congenital hypothyroidism; Hypothyroidism due to radiation therapy to the head and neck

Intervention groups
1. Vitamin D supplement group (50000 units weekly) 2. Placebo group

Main outcome variables
glycemic indices; serum level of lipid profile; thyroid hormones; serum Irisin; anthropometric measurements; vitamin D serum

General information

Reason for update

Acronym
VITDHYPOT

IRCT registration information
IRCT registration number: **IRCT20100408003664N25**
Registration date: **2021-10-23, 1400/08/01**
Registration timing: **prospective**

Last update: **2021-10-23, 1400/08/01**
Update count: **0**

Registration date
2021-10-23, 1400/08/01

Registrant information

Name
Maryam Rafraf

Name of organization / entity
Tabriz University Of Medical Sciences

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Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2021-11-06, 1400/08/15

Expected recruitment end date

2022-03-06, 1400/12/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of vitamin D supplementation on metabolic status, thyroid hormones, serum irisin and obesity indices in women with subclinical hypothyroidism

Public title

The effects of vitamin D supplementation in women with hypothyroidism

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Willingness to participate in research Women between the ages of 20 and 65 with subclinical hypothyroidism BMI 25-37 Kg / m2 TSH 5-10 micro units per milliliter and freeT3 and free T4 are normal

Exclusion criteria:

Serum Vitamin D Levels higher than 100 µg / L Smoking and alcohol Pregnancy and lactation Diabetes and infectious heart disease Kidney failure Cushing's syndrome Liver diseases Regular consumption of any dietary supplement during the last 2 months and during the study

Age

From **20 years** old to **65 years** old

Gender

Female

Phase

3

Groups that have been masked

- Participant
- Investigator

Sample size

Target sample size: **44**

Randomization (investigator's opinion)

Randomized

Randomization description

The eligible participants will be randomly allocated to intervention and placebo groups using a software-generated random permuted blocks. The generated random sequence will be kept in a protected location and administered by an independent third party who is blind to the trial throughout the study. In order to hide, a random sequence will not be provided to the executor and will be performed sequentially for each block.

Blinding (investigator's opinion)

Double blinded

Blinding description

The placebo and supplement will be packed in the same number in similar packages. The method of blindness will be that the supplements and placebo will be delivered to the participants by someone other than the researcher, and the researcher will remain unaware until the end of the study.

Placebo

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 Science

Street address

Tabriz University of Medical Science, Attar Neishabouri Avenue, Golgasht street, Tabriz

City

Tabriz

Province

East Azarbaijan

Postal code

5138663134

Approval date

2021-07-10, 1400/04/19

Ethics committee reference number

IR.TBZMED.REC.1400.327

Health conditions studied

1

Description of health condition studied

subclinical hypothyroidism

ICD-10 code

E03

ICD-10 code description

Other hypothyroidism

Primary outcomes

1

Description

Serum Vitamin D

Timepoint

Baseline and 12 weeks after the intervention

Method of measurement

ELISA

2

Description

Glycemic indexes

Timepoint

Baseline and after 12 weeks after the intervention

Method of measurement

Glycemic indexes (from indicators of metabolic status) including fasting blood sugar by enzymatic method, insulin by ELISA and insulin resistance by formula, will be measured or calculated.

3

Description
lipid profile
Timepoint
Baseline and 12 weeks after the intervention
Method of measurement
Lipid profile (from indicators of metabolic status) including total cholesterol, triglycerides and high-density lipoprotein will be measured enzymatically, and low-density lipoprotein will be calculated using the friedwald formula.

4

Description
Thyroid hormones
Timepoint
Baseline and 12 weeks after the intervention
Method of measurement
Thyroid hormones including thyroid stimulating hormone, triiodothyronine and thyroxine will be measured by ELISA.

5

Description
Irisin
Timepoint
Baseline and 12 weeks after the intervention
Method of measurement
ELISA

Secondary outcomes

1

Description
Obesity indices
Timepoint
Baseline and 12 weeks after the intervention
Method of measurement
Obesity indices including weight with scales and waist circumference and hip circumference will be measured with a tape measure. Body mass index will be calculated with the formula.

2

Description
Body composition
Timepoint
Baseline and 12 weeks after the intervention
Method of measurement
Body composition will be measured by Bio impedance (BIA) method usingTanita body composition analyzer.

3

Description
Dietary intake
Timepoint
Baseline and 12 weeks after the intervention
Method of measurement
The food record questionnaire will be used to assess food intake including energy, carbohydrate, protein and fat.

4

Description
Physical activity
Timepoint
Baseline and 12 weeks after the intervention
Method of measurement
The International Physical Activity Questionnaire will be used to measure physical activity.

Intervention groups

1

Description
Intervention group: 50000 units weekly vitamin D of Zahravi company for 3 month
Category
Treatment - Drugs

2

Description
Control group: Intake a Placebo perl containing sunflower oil, which is similar to vitamin D supplement in terms of dosage, color and size, once a week for 12 weeks
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Endocrinology clinic of Imam Reza Hospital , Tabriz
Full name of responsible person
Sara Safari
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Imam Reza Hospital, Golghast Street, Tabriz
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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Tabriz University of Medical Sciences

Full name of responsible person
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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
Sara Safari

Position
MSc Student of Nutrition Sciences

Latest degree
Bachelor

Other areas of specialty/work
Nutrition

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Other areas of specialty/work
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be a plan to make this available

Study Protocol
Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan
Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form
Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report
Undecided - It is not yet known if there will be a plan to make this available

Analytic Code
Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary
Undecided - It is not yet known if there will be a plan to make this available