Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Jul 2026

Evaluation of the effect of vitamin D supplementation on insulin resistance, lipid profile, thyroid function indices and body composition in overweight and obese patients with hypothyroidism and glucose intolerance

Protocol summary

Study aim
Determining the effect of vitamin D supplementation on insulin resistance, lipid profile, thyroid function indices, and body composition in overweight and obese patients with hypothyroidism and glucose intolerance

Design
A double-blind randomized controlled clinical at phase 3, in which 50 participants using block randomization will be randomly assigned to two groups. Participants in the control group receive vitamin D daily for 12 weeks and the control group uses a placebo in the same order.

Settings and conduct
Fifty patients who were referred to Shahid Mofteh Educational and Medical Polyclinic in Yasouj will be included in the study. After being informed and signing the informed consent form, the demographic characteristics of participants will be recorded. Participants will randomly be allocated to either intervention or control group which are named as A or B, in order to blind both investigators and participants and use relevant treatment based on their allocated groups. Anthropometrics will be assessed at the beginning and after the intervention. Blood samples will also be taken before and after the intervention to measure insulin resistance, thyroid function, and lipid profile.

Participants/Inclusion and exclusion criteria
Inclusion criteria: Overweight and obese individuals aged 20 to 75 years with hypothyroidism and glucose intolerance; and Serum vitamin D less than 30 ng/ml; Exclusion criteria: cancer, kidney, liver, cardiovascular, bone and endocrine disorders other than hypothyroidism and glucose intolerance; taking multivitamins-minerals; being pregnant or in breastfeeding duration

Intervention groups
There are two groups in this study: Intervention group: Receive 4000 IU vitamin D3 supplement daily for 12 weeks. Control group: Receive placebo daily for 12 weeks.

Main outcome variables
Insulin resistance; lipid profile; thyroid function indices, and body composition

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20210630051751N1**
Registration date: **2021-10-11, 1400/07/19**
Registration timing: **prospective**

Last update: **2021-10-11, 1400/07/19**
Update count: **0**

Registration date
2021-10-11, 1400/07/19

Registrant information

Name
Nasrin Dahesh

Name of organization / entity

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Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2021-10-12, 1400/07/20

Expected recruitment end date
2022-01-20, 1400/10/30
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Evaluation of the effect of vitamin D supplementation on insulin resistance, lipid profile, thyroid function indices and body composition in overweight and obese patients with hypothyroidism and glucose intolerance

Public title
Evaluation of the effect of vitamin D supplementation on insulin resistance, lipid profile, thyroid function indices and body composition in overweight and obese patients with hypothyroidism and glucose intolerance
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Individuals between 20 and 75 years old. Overweight or obese individuals with a body mass index above 25. Individuals Suffering from hypothyroidism with TSH levels higher than 7 microIU/ml. Individuals with impaired glucose tolerance with fasting plasma glucose levels above 100 mg/dL or 2-hour plasma glucose above 140 mg / dL. Individuals with serum 25-hydroxyvitamin D3 concentration is less than 30 ng/ml.
Exclusion criteria:
Individuals with cancer, kidney, liver, cardiovascular, bone, and endocrine diseases other than hypothyroidism and glucose intolerance disorders. Individuals taking drugs related to diseases such as cancer, kidney, liver, heart, and drugs that affect bone metabolism (estrogen, selective estrogen receptor modulator, bisphosphonate, vitamin D, or calcium). Individuals consuming multivitamins-minerals. Pregnant and lactating women.
Age
From **20 years** old to **75 years** old
Gender
Both

Phase
3
Groups that have been masked

- Participant
- Investigator
- Outcome assessor
- Data analyser

Sample size
Target sample size: **50**
Randomization (investigator's opinion)
Randomized
Randomization description
Randomization is done using the block randomization method (1: 1 ratio for intervention and control groups). In this method, blocks of two with a rotation will be created. Then one of these blocks is randomly selected to determine the allocated group for the first and second participants. After that, this random block selection process is repeated to determine the sequence of random allocation until the end of the desired sample size. After determining the randomized sequence, these sequences will be placed in sealed envelopes. The process will be done by an out-of-study person familiar with randomization. Then, when a participant enters the study, an envelope will be opened according to the order and the participant's group will be identified.
Blinding (investigator's opinion)
Double blinded
Blinding description
The capsules for the intervention and control group are the same in terms of appearance characteristics such as color, shape, and size. Capsules are named according to the intervention groups with the same names as A and B by someone outside the study who is not aware of the objectives and method of study. Therefore, both the research team and the participant are blinded to receiving the supplement or placebo.
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Committee of Shiraz University of Medical Sciences
Street address
Shiraz - Zand Alley - Central building of Fars University of Medical Sciences and Health Services
City
Shiraz
Province
Fars
Postal code
۷۱۳۴۸۱۴۳۳۶
Approval date
2021-06-19, 1400/03/29
Ethics committee reference number
IR.SUMS.REC.1400.261

Health conditions studied

1

Description of health condition studied
Hypothyroidism
ICD-10 code
E03
ICD-10 code description

Other hypothyroidism

2

Description of health condition studied
Impaired glucose tolerance
ICD-10 code
R73.02
ICD-10 code description
Impaired glucose tolerance (oral)

3

Description of health condition studied
Overweight and obesity
ICD-10 code
E66
ICD-10 code description
Overweight and obesity

Primary outcomes

1

Description
Insulin resistance: A disorder of glucose homeostasis that is defined as a decrease in the sensitivity of adipose tissue, liver, liver, and other body tissues to insulin, despite normal or elevated levels of insulin in the blood.
Timepoint
At the beginning of the study (before the intervention) and 12 weeks later at the end of the intervention
Method of measurement
Using the formula HOMA-IR: [Fasting insulin(mIU/L) × fasting glucose(mg/dL)]/405

Secondary outcomes

1

Description
Weight: Weight of a person with light minimum possible clothes and without shoes with an accuracy of 100 grams
Timepoint
At the beginning of the study (before the intervention) and 12 weeks later at the end of the intervention
Method of measurement
Scales

2

Description
BMI: [Weight(kg)]/[height (cm) * height (cm)]
Timepoint
At the beginning of the study (before the intervention) and 12 weeks later at the end of the intervention
Method of measurement
Formula

3

Description
Waist Circumference: the smallest circumference of waist in centimeters
Timepoint
At the beginning of the study (before the intervention) and 12 weeks later at the end of the intervention
Method of measurement
Tape measure

4

Description
Serum TSH
Timepoint
At the beginning of the study (before the intervention) and 12 weeks later at the end of the intervention
Method of measurement
ELISA

5

Description
Serum T3
Timepoint
At the beginning of the study (before the intervention) and 12 weeks later at the end of the intervention
Method of measurement
ELISA

6

Description
Serum T4
Timepoint
At the beginning of the study (before the intervention) and 12 weeks later at the end of the intervention
Method of measurement
Eliza

7

Description
Fasting serum insulin
Timepoint
At the beginning of the study (before the intervention) and 12 weeks later at the end of the intervention
Method of measurement
Spectrophotometer

8

Description
Fasting serum glucose
Timepoint
At the beginning of the study (before the intervention) and 12 weeks later at the end of the intervention
Method of measurement
Spectrophotometer

9

Description
HbA1c
Timepoint

At the beginning of the study (before the intervention) and 12 weeks later at the end of the intervention

Method of measurement

Spectrophotometer

10

Description

Serum LDL-c

Timepoint

At the beginning of the study (before the intervention) and 12 weeks later at the end of the intervention

Method of measurement

Spectrophotometer

11

Description

Serum HDL-c

Timepoint

At the beginning of the study (before the intervention) and 12 weeks later at the end of the intervention

Method of measurement

Spectrophotometer

12

Description

Serum total cholestrol

Timepoint

At the beginning of the study (before the intervention) and 12 weeks later at the end of the intervention

Method of measurement

Spectrophotometer

13

Description

Serum triglycerides

Timepoint

At the beginning of the study (before the intervention) and 12 weeks later at the end of the intervention

Method of measurement

Spectrophotometer

14

Description

Body Fat

Timepoint

At the beginning of the study (before the intervention) and 12 weeks later at the end of the intervention

Method of measurement

Body Analyzer

15

Description

P.B.F (Percent Body Fat)

Timepoint

At the beginning of the study (before the intervention) and 12 weeks later at the end of the intervention

Method of measurement

Body Analyzer

16

Description

Visceral fat

Timepoint

At the beginning of the study (before the intervention) and 12 weeks later at the end of the intervention

Method of measurement

Body Analyzer

17

Description

Subcutaneous fat

Timepoint

At the beginning of the study (before the intervention) and 12 weeks later at the end of the intervention

Method of measurement

Body Analyzer

18

Description

Waist to Hip Ratio

Timepoint

At the beginning of the study (before the intervention) and 12 weeks later at the end of the intervention

Method of measurement

Body Analyzer

19

Description

T.E.E (Total Energy Expenditure)

Timepoint

At the beginning of the study (before the intervention) and 12 weeks later at the end of the intervention

Method of measurement

Body Analyzer

20

Description

Serum 25- Hydroxy vitamin D

Timepoint

At the beginning of the study (before the intervention) and 12 weeks later at the end of the intervention

Method of measurement

ELISA

Intervention groups

1

Description

Intervention group: For 12 weeks, receive vitamin D3 supplement daily (containing 4000 IU of vitamin D3, produced by Zahravi Pharmaceutical Company).

Category

Treatment - Drugs

2

Description
For 12 weeks, they receive a placebo (produced by Zahravi Pharmaceutical Company, which is similar in appearance characteristics to the supplement used in the intervention group).
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Shahid Mofteh Shahid Mofteh specialized and sub-specialized polyclinic in Yasuj
Full name of responsible person
Dr. Sajjad Hassanzadeh
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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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
Shiraz 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
Shiraz University of Medical Sciences
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Nasrin Dahesh

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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