Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

The effect of some micronutrients consumption on Thyroid function, lipid profile and glycemic status in hypothyroid patients

Protocol summary

Study aim
The effect of some micronutrients including selenium, zinc, magnesium, vitamin A and vitamin D compared with placebo consumption on thyroid function, lipid profile and glycemic status in hypothyroid patients

Design
Controlled clinical trial, with parallel groups, triple blinded, randomized, phase 3, on 90 patients, non-block random allocation will be used for randomization

Settings and conduct
Hypothyroid patients referred to the hospital, after evaluating the inclusion criteria, are intervened within 8 weeks and their thyroid, lipid and glycemic factors are evaluated. Patients, researchers and data analyser are unaware of the type of intervention of each patient.

Participants/Inclusion and exclusion criteria
Hypothyroid patients candidates for levothyroxine, age 19 to 65 years, not to take vitamin D orally or by injection during the last 2-3 months, willingness to participate in the study No entry: Smoking or taking addictive drugs or alcohol, Pregnancy and breastfeeding, Chronic renal failure, diabetes, other autoimmune diseases and malignancies or taking certain medications, History of various thyroid diseases, as well as critical condition, taking dietary supplements or following a low-calorie diet through last 3 months

Intervention groups
Intervention group: One daily capsule of selenium plus supplement or an alternative, plus one daily capsule of cmz supplement or an alternative, and once a week, one of 50,000 international unit of vitamin D supplement during 8 weeks Control group: placebo capsule with the same schedule

Main outcome variables
Thyroid function (thyroid stimulating hormone, anti thyroid peroxidase), lipid profile (serum triglyceride, total cholesterole, high density lipoprotein, low density lipoprotein) and glycemic status (fasting blood sugar,fasting insulin, homeostatic model assessment for insulin resistance)

General information

Reason for update
Acronym
IRCT registration information
IRCT registration number: **IRCT20200610047719N1**
Registration date: **2022-01-31, 1400/11/11**
Registration timing: **prospective**

Last update: **2022-01-31, 1400/11/11**
Update count: **0**

Registration date
2022-01-31, 1400/11/11

Registrant information
Name
Mehrnaz Nikkhah bodaghi
Name of organization / entity
Country
Iran (Islamic Republic of)
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+98 21 86701
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Recruitment status
Recruitment complete
Funding source

Expected recruitment start date
2022-02-20, 1400/12/01
Expected recruitment end date
2023-07-21, 1402/04/30
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date

empty

Scientific title
The effect of some micronutrients consumption on Thyroid function, lipid profile and glycemic status in hypothyroid patients

Public title
The effect of some micronutrients supplementation in treatment of hypothyroidism

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Hypothyroid patients who are candidates for levothyroxine Age 19 to 65 years (both male and female) Not to take vitamin D orally or by injection during the last 2-3 months Willingness to participate in the study

Exclusion criteria:
History of various thyroid diseases Smoking or taking addictive drugs or alcohol Pregnancy and breastfeeding Chronic renal failure, dialysis, diabetes, other autoimmune diseases and malignancies or taking certain medications Critical condition in the last 3 months leading to hospitalization or cytokine use Taking a variety of multivitamin mineral or antioxidant supplements as well as following a low-calorie diet 3 months before the start of the study Participating in other clinical trials at the same time or recently

Age
From **19 years** old to **65 years** old

Gender
Both

Phase
3

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser

Sample size
Target sample size: **90**

Randomization (investigator's opinion)
Randomized

Randomization description
Eligible individuals are divided into two groups A and B by simple random allocation. A random chain of 90 repetitions of letters A and B (45 letters A and 45 letters B) is compiled by statistical website sealedenvelope.com. This sequence will be written on sheets of paper, respectively, and the sheets will be placed in similar envelopes. The corresponding sequence number will be remembered on the back of each envelope so that the envelope with the corresponding number will be opened according to the entry order.

Blinding (investigator's opinion)
Triple blinded

Blinding description
Nutrients and placebo are named as A and B by someone other than the researcher and therefore the researcher, patients and data analyzer will not know the type.

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of Iran University of Medical Sciences

Street address
Shahid Hemmat Highway

City
Tehran

Province
Tehran

Postal code
۱۴۴۹۶۱۴۵۳۵

Approval date
2022-01-26, 1400/11/06

Ethics committee reference number
IR.IUMS.REC.1400.986

Health conditions studied

1

Description of health condition studied
Hypothyroidism

ICD-10 code
E03.9

ICD-10 code description
Hypothyroidism, unspecified

Primary outcomes

1

Description
Thyroid stimulating hormone

Timepoint
Baseline and after intervention

Method of measurement
Blood test

Secondary outcomes

1

Description
Anti thyroid peroxidase

Timepoint

Baseline and after intervention

Method of measurement

Blood test

2

Description

Serum triglyceride

Timepoint

Baseline and after intervention

Method of measurement

Blood test

3

Description

Serum total cholesterol

Timepoint

Baseline and after intervention

Method of measurement

Blood test

4

Description

High density lipoprotein

Timepoint

Baseline and after intervention

Method of measurement

Blood test

5

Description

Low density lipoprotein

Timepoint

Baseline and after intervention

Method of measurement

Blood test

6

Description

Fasting blood sugar

Timepoint

Baseline and after intervention

Method of measurement

Blood test

7

Description

Serum fasting insulin

Timepoint

Baseline and after intervention

Method of measurement

Blood test

8

Description

Homeostatic model assessment for insulin resistance

Timepoint

Baseline and after intervention

Method of measurement

Calculation

Intervention groups

1

Description

Intervention group: One daily capsule of selenium plus supplement (200 micrograms sodium selenite, 4 mg zinc citrate, 120 mg vitamin C, 100 IU vitamin E , 2500 IU vitamin A) or an alternative, plus one daily capsule of cmz supplement (12.5 mg zinc, 165 mg magnesium and 525 mg calcium carbonate) or an alternative, and once a week, a perl of 50,000 IU vitamin D.during 8 weeks

Category

Treatment - Drugs

2

Description

Control group: One daily capsule of placebo of selenium plus supplement, plus one daily capsule of placebo of cmz supplement, and once a week, a perl of placebo of vitamin D during 8 weeks

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Firoozgar hospital

Full name of responsible person

Fatemeh Golgiri

Street address

Behafarin Street, Karimkhan Street, Valiasr Square, Tehran, Iran

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Iran University of Medical Sciences

Full name of responsible person

Seyed Abas Motevalian

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research-m@iums.ac.ir

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?
Yes

Title of funding source
Iran 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
Iran University of Medical Sciences

Full name of responsible person
Mehrnaz Nikkhah Bodaghi

Position
PhD student

Latest degree
Master

Other areas of specialty/work
Nutrition

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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