

Clinical Trial Protocol

Iranian Registry of Clinical Trials

02 Jun 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 cholesterol, 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)

Phone

+98 21 86701

Email address

mehrnaznikkhah@yahoo.com

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

۱۳۳۹۶۱۴۵۳۵

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,
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۱۵۹۳۷۴۷۸۱۱
Phone
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Email
h_firoozgar@yahoo.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Iran University of Medical Sciences
Full name of responsible person
Seyed Abas Motevalian
Street address
Fifth floor of the headquarters, Iran University of

Medical Sciences, Hemmat Highway, Tehran

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Phone

+98 21 8670 2504

Email

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