

# 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

۱۳۴۹۶۱۴۵۳۵

#### 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  
**City**  
Tehran  
**Province**  
Tehran  
**Postal code**  
۱۵۹۳۷۴۷۸۱۱  
**Phone**  
+98 21 8214 1600  
**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

**City**

Tehran

**Province**

Tehran

**Postal code**

۱۴۴۹۶۱۴۵۳۵

**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

**Street address**

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## Person responsible for scientific inquiries

**Contact****Name of organization / entity**

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## Person responsible for updating data

**Contact****Name of organization / entity**

Iran University of Medical Sciences

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**Email**

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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