

Clinical Trial Protocol

Iranian Registry of Clinical Trials

01 Jul 2026

Effects of Single and Combined Zinc & Selenium Supplementation on Anthropometric measurements, metabolic rate & Thyroid Hormone Concentrations in Hypothyroid Overweight or Obese Patients.

Protocol summary

Summary

We have designed a double-blind, placebo-controlled, randomized trial to investigate whether single and combined Zinc & Selenium supplementation improve anthropometric measurements, metabolic rate & thyroid hormone concentrations in Hypothyroid Overweight or Obese Patients. Sixty eight, aged 25-65 years old, hypothyroidism patients, who is eligible for this study, will be recruited from Firouzgar Hospital. Participants randomly allocated in four groups, receiving supplementation of zinc, selenium, zinc + selenium or placebo for 12 weeks. Thyroid hormone levels, resting metabolic rate & body composition will be measured at the baseline and the end of the study

General information

Acronym

Zinc & Selenium & Hypothyroidism

IRCT registration information

IRCT registration number: **IRCT201112182365N4**

Registration date: **2012-05-02, 1391/02/13**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2012-05-02, 1391/02/13

Registrant information

Name

Mohammad Reza Vafa

Name of organization / entity

Iran University of Medical Sciences

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Tehran University Of Medical sciences, vice-chancellor of research, Dr. Ali Akbar Fotohi.

Expected recruitment start date

2011-10-23, 1390/08/01

Expected recruitment end date

2011-12-21, 1390/09/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effects of Single and Combined Zinc & Selenium Supplementation on Anthropometric measurements, metabolic rate & Thyroid Hormone Concentrations in Hypothyroid Overweight or Obese Patients.

Public title

Effects of Single and Combined Zinc & Selenium Supplementation on Anthropometric measurements, metabolic rate & Thyroid Hormone Concentrations in Hypothyroid Overweight or Obese Patients.

Purpose

Supportive

Inclusion/Exclusion criteria

In this study Hypothyroid patients are recruited from Firouzgar Hospital of Tehran university of medical sciences Inclusion criteria: patients consensus; age 25 to 65 years old; BMI= 25-40 kg/m²; Exclusion Criteria: Unwillingness to continue the study; compliance below

the 80 percent; having history of Diabetes; Hypertension; cardiovascular diseases; gastrointestinal diseases; anemia; pregnant or lactating women; alcohol consumer or Cigarette smoker, Taking any supplements including vitamins & minerals in last 3 months.

Age

From **25 years** old to **65 years** old

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **68**

Randomization (investigator's opinion)

Randomized

Randomization description**Blinding (investigator's opinion)**

Double blinded

Blinding description**Placebo**

Used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Tehran University of Medical Sciences, School of Public health

Street address

Arjantin Square, Alvand Avenue, School of Public Health

City

Tehran

Postal code**Approval date**

2012-04-24, 1391/02/05

Ethics committee reference number

49454

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 Hormones

Timepoint

12 weeks

Method of measurement

Radioimmunoassay

Secondary outcomes**1****Description**

Body Composition

Timepoint

12 weeks

Method of measurement

Body Composition Analyser

2**Description**

Basal Metabolic Rate

Timepoint

12 weeks

Method of measurement

Body Composition Analyser

Intervention groups**1****Description**

Dietary Zinc supplement, 30 mg/d and dietary Selenium supplement 200 µg/d for 12 weeks

Category

Treatment - Other

2**Description**

Placebo, the same as zinc tablet as the active supplement with the same size, daily for 12 weeks and Placebo, the same as selenium tablet as the active supplement with the same size, daily for 12 weeks.

Category

Placebo

3**Description**

Dietary Zinc supplement, 30 mg, daily for 12 weeks , and Placebo, the same as selenium tablet as the active supplement with the same size, daily for 12 weeks.

Category

Treatment - Drugs

4

Description

Dietary selenium supplement, 200 µg, daily for 12 weeks , and Placebo, the same as zinc tablet as the active supplement with the same size, daily for 12 weeks.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Firouzgar Endocrinology Clinic

Full name of responsible person

Mohammad Reza Vafa

Street address

City

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Mohammad Reza Vafa

Street address

Arjantin Square, Alvand Avenue, School of Public Health

City

Tehran

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Tehran University of Medical Sciences

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

empty

Person responsible for general inquiries

Contact

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Mohammad Reza Vafa

Position

Associate Professor

Other areas of specialty/work

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty