

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

The effects of Zn, vitamin A and magnesium supplementation on anthropometric parameters, metabolic, thyroid hormones, oxidative stress and hs-CRP in patients with hypothyroidism

Protocol summary

Summary

We have designed a double-blind, placebo-controlled, randomized trial to investigate whether combined zinc, vitamin A and magnesium supplementation improve anthropometric measurements, metabolic rate, thyroid hormone, oxidative stress and hs-CRP concentrations in Hypothyroid Patients. eighty eight, aged 20-65 years old, hypothyroidism patients, who is eligible for this study, will be recruited from Endocrine and Metabolism Research Institute of Iran University of Medical Sciences. Participants randomly allocated in two groups, receiving supplementation of zinc, vitamin A and magnesium or placebo for 10 weeks. Thyroid hormone levels, resting metabolic rate, body composition, oxidative stress and hs-CRP will be measured at the baseline and the end of the study

General information

Acronym

zinc AND vitamin A and magnesium and hypothyroidism

IRCT registration information

IRCT registration number: **IRCT201709042365N17**

Registration date: **2017-09-23, 1396/07/01**

Registration timing: **prospective**

Last update:

Update count: **0**

Registration date

2017-09-23, 1396/07/01

Registrant information

Name

Mohammad Reza Vafa

Name of organization / entity

Iran University of Medical Sciences

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Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

vice chancellor of research, Iran University of Medical Sciences

Expected recruitment start date

2017-10-01, 1396/07/09

Expected recruitment end date

2018-07-01, 1397/04/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effects of Zn, vitamin A and magnesium supplementation on anthropometric parameters, metabolic, thyroid hormones, oxidative stress and hs-CRP in patients with hypothyroidism

Public title

The effects of Zn, vitamin A and magnesium supplementation on patients with hypothyroidism

Purpose

Supportive

Inclusion/Exclusion criteria

Hypothyroid patients referring to Endocrine and Metabolism Research Institute of Iran University of Medical Sciences who have the following criteria and express their willingness to cooperate. Inclusion criteria: patients consensus; age 20 to 65 years old; BMI < 30

kg/m²; Drug therapy with levothyroxine; 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; digestive complications for supplements; Changing the dosage of the drug in the study

Age

From **20 years** old to **65 years** old

Gender

Both

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **88**

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

Iran University of Medical Sciences

Street address

Hemmat Highway, IUMS

City

Tehran

Postal code

Approval date

2017-09-02, 1396/06/11

Ethics committee reference number

IR.IUMS.FMD.REC 1396.9411468007

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

Before intervention and 10 weeks after intervention

Method of measurement

ELIZA

Secondary outcomes

1

Description

MDA

Timepoint

Before intervention and 10 weeks after intervention

Method of measurement

measurement kit

2

Description

hs-CRP

Timepoint

Before intervention and 10 weeks after intervention

Method of measurement

ELIZA

3

Description

Body Composition

Timepoint

Before intervention and 10 weeks after intervention

Method of measurement

Body Composition Analyser

4

Description

Basal Metabolic Rate

Timepoint

Before intervention and 10 weeks after intervention

Method of measurement

Body Composition Analyser

5

Description

TAC

Timepoint

Before intervention and 10 weeks after intervention

Method of measurement

measurement kit

Intervention groups

1

Description

Dietary Zinc supplement, 30 mg/d. Dietary vitamin A supplement, 25000 IU twice a week and Dietary magnesium supplement, 250 mg/d for 10 weeks

Category

Treatment - Other

2

Description

Placebo, the same as zinc tablet as the active supplement with the same size, daily for 10 weeks.
Placebo, the same as magnesium tablet as the active supplement with the same size, daily for 10 weeks and
Placebo, the same as vitamin A capsule as the active supplement with the same size, twice a week for 10 weeks

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Iran University of Medical Sciences

Full name of responsible person

Dr. Mohammad Reza Vafa

Street address

City

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Iran University of Medical Sciences

Full name of responsible person

Seyed Alijavad Moosavi

Street address

University Research Assistant, Headquarter Bulding,
Iran University Of Medical Sciences, Beside Milad
hospital, Shahid Hemat high way, Tehran, Iran

City

tehran

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

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

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Full name of responsible person

Dr Mohammad Reza Vafa

Position

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