Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 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 measurments, 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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Recruitment status

Recruitment complete

Funding source

vice chanceller 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 and10 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
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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
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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

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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