Clinical Trial Protocol
Iranian Registry of Clinical Trials

30 May 2026

The effects of Zinc, vitamin D supplementation and co-supplementation of them versus placebo on lipid profile in overweight and obese subjects

Protocol summary

Study aim
comparison of lipid profiles between zinc supplementation , vitamin D supplementation, zinc and vitamin D supplementation and placebo groups before and after intervention

Design
Two arms parallel group randomized trial with blinded postoperative care

Settings and conduct
This double-blind, randomized, placebo-controlled clinical trial study was conducted in 140 obese patients referring to Imam Khomeini Hospital Endocrine Research Center.All assessments were made at baseline and after 12 weeks of intervention.Randomization assignment as blinding was done using computer-generated random numbers by a trained statistical staff.

Participants/Inclusion and exclusion criteria
Inclusion criteria: age between 20 to 60 years old; BMI greater than 27; willing to participate; weight stable in 3 last months. Exclusion criteria: having a history of coronary artery disease; acute or chronic renal failure; acute or chronic hepatic failure; presence of any chronic 2 inflammatory and autoimmune disease; and any known malignancy; hormone therapy; other non-pathological exclusion criteria included pregnancy; breast feeding; post-menopause; smoking, professional athlete; uncontrolled thyroid disorder; use of medications for dyslipidemia or hypertension; having a special diet for any reason prescribed by the clinic dietitian; consumption of nutritional supplements within the past 12 weeks.

Intervention groups
Intervention groups consume: (1) 2,000 U/day vitamin D + zinc placebo or (2) 30 mg/day zinc + vitamin D placebo or (3) 2,000 U/day vitamin D + 30 mg/day zinc every day for 12 weeks. In the control group daily, 1 zinc placebo (containing starch) and 1 placebo of vitamin D (containing starch) will be taken for 12 weeks

Main outcome variables
Lipid profile

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20180910040997N1**
Registration date: **2019-04-20, 1398/01/31**
Registration timing: **retrospective**

Last update: **2019-04-20, 1398/01/31**
Update count: **0**

Registration date
2019-04-20, 1398/01/31

Registrant information

Name
Somayeh Yosaee

Name of organization / entity

Country
Iran (Islamic Republic of)

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+98 71 2248 0864

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2018-11-02, 1397/08/11

Expected recruitment end date
2019-04-19, 1398/01/30

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date

empty

Scientific title
The effects of Zinc, vitamin D supplementation and co-supplementation of them versus placebo on lipid profile in overweight and obese subjects

Public title
The effects of Zinc, vitamin D supplementation and co-supplementation of them versus placebo on lipid profile in overweight and obese subjects

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
age between 20 to 60 years old BMI greater than 27 willing to participate weight stable in 3 last months

Exclusion criteria:
having a history of coronary artery disease; acute or chronic renal failure;acute or chronic hepatic failure; presence of any chronic inflammatory and autoimmune disease; and any known malignancy use of vitamin and mineral supplement in 3 last months smoking Use of any type of drug including anti-inflammatory drugs (NSAIDs, salicylates, steroids), aminoglycoside antibiotics, blood pressure control drugs and blood glucose professional athlete having a special diet for any reason prescribed by the clinic dietitian A person's desire to have a weight loss diet

Age
From **20 years** old to **60 years** old

Gender
Both

Phase
3

Groups that have been masked

- Participant
- Investigator

Sample size
Target sample size: **140**

Randomization (investigator's opinion)
Randomized

Randomization description
Random allocation method: block randomization with block size 8 Random allocation unit: individual Random allocation approaches: Random number table

Blinding (investigator's opinion)
Double blinded

Blinding description
All subjects and participants in the research will be blind to the process of allocation of treatment and treatment groups.

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of Larestan school of medical science

Street address
Deputy of research, Larestanschool of medical sciences, New city,Dadman Highway, larestan, Iran

City
Larestan

Province
Fars

Postal code
7476154538

Approval date
2018-10-01, 1397/07/09

Ethics committee reference number
IR.LARUMS.REC.1397.007

Health conditions studied

1

Description of health condition studied
Obesity

ICD-10 code
E66.0

ICD-10 code description
Obesity due to excess calories

Primary outcomes

1

Description
Serum level of lipid profile including Triglyceride, HDL, LDL, TC

Timepoint
Before and 12 weeks after intervention

Method of measurement
Serum concentration of lipid profile (TG, TC, LDL, HDL)

Secondary outcomes

empty

Intervention groups

1

Description
(1) 2,000 U/day vitamin D+ zinc placebo

Category
Treatment - Drugs

2

Description
30 mg/day zinc + vitamin D placebo

Category
N/A

3

Description
2,000 U/day vitamin D + 30 mg/day zinc
Category
N/A

4

Description
Zinc placebo + vitamin D placebo
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Imam Khomeini Hospital Endocrine Research Center
Full name of responsible person
Somayeh Yousaee
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Deputy of Research, Larestanschool of Medical Sciences, New City,Dadman Highway, Larestan, Iran
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Larestan University of Medical Sciences
Full name of responsible person
Dr. Zahra Keshtkaran
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Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Larestan 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
Larestan University of Medical Sciences
Full name of responsible person
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Position
Associate professor
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Person responsible for updating data

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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
Not applicable

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
Not applicable

Data Dictionary
Not applicable