

# 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 Yosae

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 71 2248 0864

##### Email address

s.yosae@larums.ac.ir

##### 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 Yousoae

**Street address**

Deputy of Research, Larestanschool of Medical Sciences, New City,Dadman Highway, Larestan, Iran

**City**

Larestan

**Province**

Fars

**Postal code**

7476154538

**Phone**

+98 71 5234 2877

**Email**

s\_yousai2006@yahoo.com

**Sponsors / Funding sources****1****Sponsor****Name of organization / entity**

Larestan University of Medical Sciences

**Full name of responsible person**

Dr. Zahra Keshtkaran

**Street address**

Deputy of Research, Larestan School of Medical sciences, New city,Dadman Highway, Larestan, Iran

**City**

Larestan

**Province**

Fars

**Postal code**

07152342877

**Phone**

+98 71 5234 2877

**Email**

s.yosae@larums.ac.ir

**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**

Somaye Yosae

**Position**

Associate professor

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Nutrition

**Street address**

Deputy of research, Larestanschool of medical sciences, New city,Dadman Highway, Larestan, Iran

**City**

Larestan

**Province**

Fars

**Postal code**

07152342877

**Phone**

+98 71 5234 2877

**Email**

s\_yousai2006@yahoo.com

**Person responsible for scientific inquiries****Contact****Name of organization / entity**

Larestan University of Medical Sciences

**Full name of responsible person**

Somaye Yosae

**Position**

Associate professor

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Nutrition

**Street address**

Deputy of research, Larestan school of medical

sciences, New city,Dadman Highway, Larestan, Iran

**City**

Larestan

**Province**

Fars

**Postal code**

07152342877

**Phone**

+98 71 5234 2877

**Email**

s\_yousai2006@yahoo.com

## Person responsible for updating data

**Contact**

**Name of organization / entity**

Larestan University of Medical Sciences

**Full name of responsible person**

Somaye Yosae

**Position**

Associate professor

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Nutrition

**Street address**

Deputy of research, Larestanschool of medical sciences, New city,Dadman Highway, Larestan, Iran

**City**

Larestan

**Province**

Fars

**Postal code**

07152342877

**Phone**

+98 71 5234 2877

**Email**

s\_yousai2006@yahoo.com

## 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