

Clinical Trial Protocol

Iranian Registry of Clinical Trials

31 May 2026

The effects of Zinc, vitamin D supplementation and co-supplementation of them versus placebo on adipokines and indicators related to metabolism in over weight and obese subjects

Protocol summary

Summary

Available literature suggests obese individuals have lower blood concentrations of vitamins D and zinc compared to non-obese individuals. Insulin-like growth factor (IGF)-system and adipokines play critical roles in regulating energy balance. There is limited information on how vitamins D and zinc affect biomarker of regulating energy hemostasis. This study was performed to assess the effects of vitamin D and zinc supplementation on the IGF-system and adipokines of obese participants. In a 2 x 2 factorial design randomised placebo controlled clinical trial, a total of 140 obese individuals aged >20 years, were recruited from the Iran University of Medical Science. Participants were randomly assigned to four groups receiving: (1) 2,000 IU/day vitamin D + zinc placebo; (2) 30 mg/day zinc + vitamin D placebo; (3) 2,000 IU/day vitamin D + 30 mg/day zinc; or (4) vitamin D placebo + zinc placebo for 12 weeks. A study technician carried out the random allocations using a random numbers table. All investigators, participants and laboratory technicians were blinded to the random assignments. All participants provided 3 days of dietary records and 3 days of physical activity records throughout the intervention. Blood samples were taken to quantify serum level adipokines and IGF and IGF binding protein 3 (IGFBP-3) at study baseline and after 12 weeks of intervention.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201608082365N13**
Registration date: **2016-08-26, 1395/06/05**
Registration timing: **prospective**

Last update:

Update count: **0**

Registration date

2016-08-26, 1395/06/05

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

Iran University of Medical Sciences

Expected recruitment start date

2016-09-01, 1395/06/11

Expected recruitment end date

2018-09-01, 1397/06/10

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 adipokines and indicators related to metabolism in over weight and obese subjects

Public title

The effects of Zinc, vitamin D supplementation and co-

supplementation of them versus placebo on adipokines and indicators related to metabolism in over weight 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; 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.

Age

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

Gender

Both

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **140**

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 of Sciences

Street address

Iran University of Medical of Sciences, Hemmat Highway, 1449614535, Tehran, Iran

City

Tehran

Postal code

74761568

Approval date

2016-07-11, 1395/04/21

Ethics committee reference number

IR.IUMS.REC 1395.9221324206

Health conditions studied

1

Description of health condition studied

Obesity

ICD-10 code

E66

ICD-10 code description

Obesity due to excess calories

Primary outcomes

1

Description

Serum level of leptin

Timepoint

Before and 12 weeks after intervention

Method of measurement

Serum concentration of leptin with Laboratory Kit

Secondary outcomes

1

Description

Insulin-like growth factor-1

Timepoint

Before and 12 weeks after intervention

Method of measurement

Serum concentration with Laboratory Kit (Mediagnose; Germany)

Intervention groups

1

Description

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

Category

Treatment - Drugs

2

Description

Control group: Consume 2 pill placebo of vitamin D and zinc contained maltodextrin ("Roshd" Pharmaceutical Incubation Center of Tehran University of Medical Sciences) every day for 12 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

Iran University of Medical Sciences, School of Public Health

City

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice Chancellor of Research, Iran University of Medical Sciences

Full name of responsible person

Dr Ali Javad Moosavi

Street address

Vice Chancellor of Research, Iran University of Medical Sciences, Hemat Express way, Tehran

City

Tehran

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Vice Chancellor of Research, 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

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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