

Clinical Trial Protocol

Iranian Registry of Clinical Trials

05 Jun 2026

The Effect of Zinc Supplementation on Appetite Regulatin Hormones in Obese Adults with High Appetite and Zinc Deficiency

Protocol summary

Study aim

The effect of zinc supplementation on the serum level of leptin, ghrelin, C-reactive protein and anthropometric indices in obese individuals with increased appetite and zinc deficiency

Design

Placebo controlled clinical trial, double blinded randomized ,on 50 individuals were randomly allocated to either zinc or placebo groups Blocked randomization(within fixed block size of four) produced by random allocation software.

Settings and conduct

People who referred to nutrition ward of Imam Reza Clinic in Shiraz,Iran were screened to find eligible participants and after obtaining written informed consent, to determine the serum zinc concentration, blood samples were collected, and only those with serum concentration less than 70 mcg/dl were considered to participate in the study.

Participants/Inclusion and exclusion criteria

Age 25-55 year Serum zinc less than 70 microgram/deciliters Body mass index(BMI) more than 30 kilogram/square meters Appetite questionnaire score more than 20 ; Absence of vitamin and mineral supplements use over the past 2 months Absence of using any weight loss products or diet Absence of the liver, kidney, thyroid, diabetes, AIDS and other metabolic diseases Lack of using lipid lowering, blood-thinning and beta-blocker drugs

Intervention groups

The zinc group had received a capsule containing 30 mili gram zinc gluconate per day, while the control group had received a capsule contaning 30 miligram indigestible starch as placebo.

Main outcome variables

Leptin, ghrelin , C-Reactive Protein (CRP)

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20201018049061N1**

Registration date: **2020-11-30, 1399/09/10**

Registration timing: **retrospective**

Last update: **2020-11-30, 1399/09/10**

Update count: **0**

Registration date

2020-11-30, 1399/09/10

Registrant information

Name

Narjes Zare

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 71 3725 1007

Email address

narjeszare3@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-02-20, 1396/12/01

Expected recruitment end date

2018-06-21, 1397/03/31

Actual recruitment start date

2018-02-20, 1396/12/01

Actual recruitment end date

2018-08-22, 1397/05/31

Trial completion date

2018-08-22, 1397/05/31

Scientific title

The Effect of Zinc Supplementation on Appetite Regulation Hormones in Obese Adults with High Appetite and Zinc Deficiency

Public title

Effect of Zinc in Obesity

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria:

BMI > 30 kg/m² Serum zinc < 70 mcg/dl Appetite questionnaire score > 20

Exclusion criteria:

Vitamin and supplements use over the past 2 months
Diet or weight loss products use recently
Presence of liver, kidney, thyroid, diabetes, AIDS and other metabolic diseases
Using lipid lowering, blood-thinning and beta-blocker drugs

Age

From **25 years** old to **55 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Participant
- Care provider
- Investigator

Sample size

Target sample size: **50**

Actual sample size reached: **50**

Randomization (investigator's opinion)

Randomized

Randomization description

In order to assign the eligible participants to the two groups, the stratified blocked randomization method was used. The block size is calculated as the sum of two allocation to the intervention group (A) and two allocation to the placebo group (B) that are created in six permutation groups, BAAB, ABBA, BBAA, BABA, ABAB, AABB. Randomization is performed using computer software.

Blinding (investigator's opinion)

Double blinded

Blinding description

The manufacturer closes the capsule in the same packages and identifies them with the names A and B and do not know the nature of them until after the study.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Shiraz University of Medical Sciences

Street address

The Scoll of Nutrition and Food Sciences, Razi Blvd

City

Shiraz

Province

Fars

Postal code

71348-14336

Approval date

2017-11-27, 1396/09/06

Ethics committee reference number

IR.SUMS.REC.1396.125

Health conditions studied

1

Description of health condition studied

Obesity

ICD-10 code

E66

ICD-10 code description

Overweight and obesity

Primary outcomes

1

Description

Serum level of leptin

Timepoint

At entry and 3 month after zinc supplementation

Method of measurement

ELISA method

2

Description

Serum level of ghrelin

Timepoint

At entry and 3 month after zinc supplementation

Method of measurement

ELISA method

3

Description

Serum level of C-Reactive Protein (CRP)

Timepoint

At entry and 3 month after zinc supplementation

Method of measurement

Immunoturbidimetric method

4

Description

Serum zinc concentration

Timepoint

At entry and 3 month after zinc supplementation

Method of measurement

Atomic absorption spectrometry

Secondary outcomes**1****Description**

Body Mass Index (BMI)

Timepoint

At entry, week 6 and 3 month after zinc supplementation

Method of measurement

Weight in Kilograms divided by height in metres squared

2**Description**

Waist to Hip Ratio (WHR)

Timepoint

At entry, week 6 and 3 month after zinc supplementation

Method of measurement

Waist circumference divided by hip circumference

Intervention groups**1****Description**

Intervention group: Consumption of a capsule containing 30 mg zinc gluconate (manufactured by nature made) per day for 3 months

Category

Treatment - Other

2**Description**

Control group: Consumption of a capsule containing 30 mg indigestible starch per day for 3 months

Category

Placebo

Recruitment centers**1****Recruitment center****Name of recruitment center**

Nutrition ward of Imam Reza Clinic

Full name of responsible person

Dr Zohre Mazloom

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Web page address**Sponsors / Funding sources****1****Sponsor****Name of organization / entity**

Shiraz University of Medical Sciences

Full name of responsible person

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Web page address**Grant name****Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Shiraz 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**

Shiraz University of Medical Sciences

Full name of responsible person

Narjes Zare

Position

Student

Latest degree

Bachelor

Other areas of specialty/work

Nutrition

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Person responsible for scientific inquiries

Contact

Name of organization / entity

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Professor

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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

Undecided - It is not yet known if there will be a plan to make this available

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

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available