Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 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 Regulatin 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 consentration

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 circemference

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
Siavash Baba Jafari Esfand Abad
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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
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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
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