Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 2026

Effects of Zinc supplementation on anthropometric factors, Apelin and inflammatory markers in obese individual

Protocol summary

Summary

Method of this study has designed based on Double blind Randomized Clinical Trial principles.the goal of this study is the Effects of combined administration of weight reducing diet and Zinc supplementation on anthropometric factors, Apelin and inflammatory markers in obese individual. in this study cases were chosen from obese patients(BMI ≥ 30 kg/m2) with no exclusion criteria.After completing informed consent form, obese patients will be requested to be fast for 12 to 14 hours in subsequent presence.then we will catch 5 cc venous blood from patients and they will be weighed with 100 grams precision and light clothing and will be calculated their stature without shoes with 0.5 cm precision and waist circumference and bioelectrical impedance analysis and their general characteristic will be record in data collecting sheet.then cases will be divided to two groups.one group (case group) will be received combined administration of weight reducing diet and zinc sulphate capsules and the other group (control group) will be received weight reducing diet and placebo. obese patients in case group will recieve 50 mg zinc daily during 15 weeks, while obese patients in control group will be recieve placebo capsules. At the end of seventh week of study, in all patients anthropometric indices, weight, waist circumference and body fat composition will be again calculated.At the end of the fifteenth week,5 cc blood after 12 to 14 hours fasting will be again catch from patients and anthropometric indices (weight, waist circumference and body fat composition) will be again recorded.finally blood samples will be santrifuge for15 minutes at 2000 rpm to separating serum component.then serum TNF-alpha, hs-CRP and Apelin will be measured with enzymatic method.In this study sample size according to standard deviation (SD) of previous studies and equality of variance in two groups based on formula for each group has calculated 15 patients that because of probable infusion, 25 patients in each group has considered

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2015072615968N2**
Registration date: **2015-09-01, 1394/06/10**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2015-09-01, 1394/06/10

Registrant information

Name
Atoosa Saidpour
Name of organization / entity
Shahid Beheshti University of Medical Sciences, School of nutrition
Country
Iran (Islamic Republic of)
Phone
-
Email address
a.saidpour@sbmu.ac.ir

Recruitment status

Recruitment complete

Funding source

National Nutrition and Food Technology Research Institute

Expected recruitment start date

2015-08-01, 1394/05/10

Expected recruitment end date

2015-12-01, 1394/09/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title
Effects of Zinc supplementation on anthropometric factors, Apelin and inflammatory markers in obese individual

Public title
Effects of Zinc supplementation in obesity
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria: aged 45-18 years; non-smoking; body mass index above 30 kg/m2 Exclusion criteria: pregnancy; lactation; menopause in women; a history of liver disease; kidney disease; thyroid; diabetes and other metabolic diseases; drugs interfering with lipid profile; blood-thinning drugs; beta-blockers; patients with immune deficiency; zinc supplementation; calcium and iron in 2 months; use of weight loss drugs or diet; weight loss diet in the last 2 months; recent surgery
Age
From **18 years** old to **45 years** old
Gender
Both

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **50**
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
National Nutrition and Food Technology Research Institute
Street address
Tehran, qods(qarb) town,shahid farahzadi boulevard,shahid hafezi (west arqavan) street,7 tag
City
Tehran
Postal code
Approval date
2015-04-21, 1394/02/01
Ethics committee reference number
055570

Health conditions studied

1

Description of health condition studied
obesity
ICD-10 code
E65, E66
ICD-10 code description
Localized adiposity, Obesity

Primary outcomes

1

Description
Body mass Index
Timepoint
before intervention, seven weeks after intervention,fifteen weeks after intervention
Method of measurement
calculating

2

Description
weight
Timepoint
before intervention, seven weeks after intervention,fifteen weeks after intervention
Method of measurement
Seca scale

3

Description
waist circumference
Timepoint
before intervention, seven weeks after intervention,fifteen weeks after intervention
Method of measurement
meter

4

Description
Hip circumference
Timepoint
before intervention, seven weeks after intervention,fifteen weeks after intervention
Method of measurement
meter

5

Description
waist circumference to hip ratio
Timepoint

before intervention, seven weeks after intervention,fifteen weeks after intervention

Method of measurement

calculating

6

Description

Body fat percentage

Timepoint

before intervention, seven weeks after intervention,fifteen weeks after intervention

Method of measurement

Bioelectrical Impedance Analysis

Secondary outcomes

1

Description

serum TNF-alpha concentration

Timepoint

before intervention,fifteen weeks after intervention

Method of measurement

Enzymatic method by kit

2

Description

hs-CRP concentration

Timepoint

before intervention,fifteen weeks after intervention

Method of measurement

Enzymatic method by kit

3

Description

Apelin concentration

Timepoint

before intervention,fifteen weeks after intervention

Method of measurement

Enzymatic method by kit

Intervention groups

1

Description

control group: obese patients in the control group receive a placebo daily for 15 weeks similar to sulfate capsule on the intervention group

Category

Placebo

2

Description

intervention group: Obese individuals in the intervention group received 50 mg of zinc sulfate for 15 weeks. .

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Clinical Nutrition and Diet Therapy Clinic of Shahid Beheshti university of medical sciences

Full name of responsible person

Hoda KHorsandi

Street address

tehran,garb town,baran street

City

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

National Nutrition and Food Technology Research Institute

Full name of responsible person

Dr.Fatemeh Mohammadi Nasrabadi

Street address

Tehran, qods(qarb) town,shahid farahzadi boulevard,shahid hafezi (west arqavan) street,7 tag

City

Tehran

Grant name

Grant code / Reference number

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

Yes

Title of funding source

National Nutrition and Food Technology Research Institute

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

National Nutrition and Food Technology Research Institute

Full name of responsible person

Hoda Khorsandi

Position

MS Student of Nutrition

Other areas of specialty/work

Street address

Tehran, qods(qarb) town,shahid farahzadi boulevard,shahid hafezi (west arqavan) street,7 tag

City

Tehran

Postal code

Phone

+98 21223574835

Fax

Email

hoda.khorsandi@yahoo.com

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity

Shahid Beheshti university of medical sciences-school of nutritio

Full name of responsible person

Dr. Atoosa Saidpour

Position

PHD of nutrition

Other areas of specialty/work

Street address

Tehran, qods(qarb) town,shahid farahzadi boulevard,shahid hafezi (west arqavan) street,7 tag

City

Tehran

Postal code

Phone

+98 21 2235 7484

Fax

Email

atoosa.saidpour@gmail.com

Web page address

Person responsible for updating data

Contact

Name of organization / entity

National Nutrition and Food Technology Research Institute

Full name of responsible person

Hoda Khorsandi sani

Position

MS Student of Nutrition

Other areas of specialty/work

Street address

Tehran, qods(qarb) town,shahid farahzadi boulevard,shahid hafezi (west arqavan) street,7 tag

City

Tehran

Postal code

Phone

00

Fax

Email

Web page address

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