

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

12 Jun 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  $\geq$  30 kg/m<sup>2</sup>) 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 receive 50 mg zinc daily during 15 weeks, while obese patients in control group will be receive 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 centrifuge for 15 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/m<sup>2</sup> 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**

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**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*