

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

Effects of zinc supplementation on mood, serum inflammatory factors and antropometric indices in obese subjects

Protocol summary

Summary

1. Objectives: Previous studies have shown that serum zinc is lower in obese subjects and low serum zinc is associated with depression. The aim of the present study is to determine effects of zinc supplementation on mood, serum inflammatory factors and anthropometric indices in obese subjects. 2.Design: double blind randomized placebo controlled trial 3. Setting and conduct: Fifty obese subjects will be randomly allocated into two groups to receive daily either 30 mg zinc or placebo for 12 weeks. Ten milliliters of fasting blood samples will be collected at baseline and after intervention. Mood state, serum inflammatory factors and anthropometric indices will be measured at the baseline and after intervention. 4. Participants : Healthy obese subjects aged 18-35 years with a BMI $\geq$ 30 Kg/lm² who are not pregnant and do not smoke. 5.Intervention: 30 mg zinc or placebo for 12 weeks 6.Main outcome measures variables: mood state, CRP, TNF- α , weight and body composition

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201106122394N5**

Registration date: **2012-04-04, 1391/01/16**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2012-04-04, 1391/01/16

Registrant information

Name

Shima Jazayeri

Name of organization / entity

Iran University of Medical Sciences

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Recruitment status

Recruitment complete

Funding source

Vice Chancellor of Research, Tehran University of Medical Sciences

Expected recruitment start date

2011-01-02, 1389/10/12

Expected recruitment end date

2011-07-02, 1390/04/11

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effects of zinc supplementation on mood, serum inflammatory factors and antropometric indices in obese subjects

Public title

Effects of zinc supplementation on mood, serum inflammatory factors and antropometric indices in obese subjects

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria: Willing to participate; Age 18 to 35 years old; BMI $\geq$ 30 Kg/m²; Being healthy; Not Taking any supplements or drugs during the previous 3 months; Exclusion criteria: Pregnancy; lactation; Smoking;

Age

From **18 years** old to **35 years** old

Gender

Both

Phase

3

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**

Ethics committee of Tehran University of Medical Sciences

Street address

Tehran University of Medical Sciences, Ghods St., Keshavarz Blvd, Tehran, Iran.

City

Tehran

Postal code**Approval date**

2011-12-25, 1390/10/04

Ethics committee reference number

13515

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**

Mood

Timepoint

At baseline, after 12 weeks

Method of measurement

Beck Depression Inventory

2**Description**

hsCRP

Timepoint

At baseline, after 12 weeks

Method of measurement

ELISA

3**Description**TNF α **Timepoint**

At baseline, after 12 weeks

Method of measurement

ELISA

4**Description**

Weight

Timepoint

At baseline, after 12 weeks

Method of measurement

Weighting

5**Description**

Body composition

Timepoint

At baseline, after 12 weeks

Method of measurement

Bioelectrical impedance analysis (BIA)

Secondary outcomes

empty

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

Zinc supplement: 30mg daily, after lunch for 12 weeks

Category

Prevention

2**Description**

Placebo: one tablet daily, after lunch, for 12 weeks.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Tehran University of Medical Sciences

Full name of responsible person

Zahra Solati, Master Student

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Tehran University of Medical Sciences, Pour Sina St.,
Enghelab Sq.

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice-chancellor for research, Tehran University of
Medical Sciences

Full name of responsible person

Dr. Akbar Fotouhi

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Tehran University of Medical Sciences, Ghods Street,
Keshavarz Blvd, Tehran, Iran

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Grant name

Grant code / Reference number

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

Yes

Title of funding source

Vice-chancellor for research, Tehran 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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Position

Student

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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