Clinical Trial Protocol
Iranian Registry of Clinical Trials

03 Jun 2026

Evaluation and comparison of zinc and omega 3 fatty acids supplementation on leptin level in obese peoples

Protocol summary

Summary

This study is a randomized double-blind placebo controlled trial that subject with BMI=30-40 kg/m2 will be recruited from clinics of Tabriz university of medical science. The aim of the study is evaluation and comparison of zinc and omega 3 fatty acids supplementation on leptin level in obese peoples. Patients will be divided randomly to 3 groups; zinc group, omega 3fatty acids and placebo. Zinc group receive 1 pill of zinc per day containing 30 mg, omega 3 fatty acid group receive 2 omega3 capsules with 1 g weight or 2 placebo capsules containing starch for a period of 30 day. Groups will not contact together. Anthropometric measurements (weight, height), biochemical criteria including plasma level of zinc and serum leptin using 5cc blood sample collected from patients, appetite evaluation, 3 dietary record will be measured before and after treatment and will be compared between three groups.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201112222017N5**
Registration date: **2012-01-10, 1390/10/20**
Registration timing: **prospective**

Last update:
Update count: **0**

Registration date

2012-01-10, 1390/10/20

Registrant information

Name

Alireza Ostadrahimi

Name of organization / entity

Tabriz University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 41 1335 7580

Email address

ostadrahimi@tbzmed.ac.ir

Recruitment status

Recruitment complete

Funding source

Nutritional Research Center

Expected recruitment start date

2012-01-21, 1390/11/01

Expected recruitment end date

2012-03-20, 1391/01/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation and comparison of zinc and omega 3 fatty acids supplementation on leptin level in obese peoples

Public title

Evaluation and comparison of zinc and omega 3 fatty acids supplementation on leptin level in obese peoples

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: BMI=30-40 and age 18-45 yrs.
Exclusion criteria: Pregnancy and lactation; menopause; medical history of diabetes mellitus, liver, kidney and thyroid disorders; HIV disease; any interfering medication with lipid profile; receiving beta blocker medications, Omega3 fatty acids, vitamin A , iron, zinc and calcium supplementation; weight lowering drugs or special diet in the past 2 months and smoking.

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: **90**

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
Vice-chancellor for research-Tabriz University of Medical Science

Street address
Golgasht street, Tabriz.East Azarbayjan, Iran, Islamic Republic Of

City
Tabriz

Postal code

Approval date
2011-04-05, 1390/01/16

Ethics committee reference number
5.4.263

Health conditions studied

1

Description of health condition studied
Obesity

ICD-10 code
E66.0

ICD-10 code description
Obesity due to excess calories

Primary outcomes

1

Description
Leptin

Timepoint
Baseline and at the end of intervention

Method of measurement
Radioimmunoassay (kit)

Secondary outcomes

1

Description
Nutritional status

Timepoint
Baseline and at the end of intervention

Method of measurement
Dietary record and food frequency questionnaire

2

Description
Plasma Zinc concentration

Timepoint
Baseline and at the end of intervention

Method of measurement
Atomic absorption spectrophotometry

3

Description
Appetite level

Timepoint
Baseline and at the end of intervention

Method of measurement
Visual analog scale questionnaire

4

Description
Anthropometric measurements

Timepoint
Baseline and at the end of intervention

Method of measurement
Analogue scale and meter

Intervention groups

1

Description
Intervention group1: 2 omega3 capsula with 1 gr weight(containing 180 mg EPA and 110 mg DHA) for 30 day

Category
Treatment - Drugs

2

Description
1 zinc pill (containing 30 mg zinc) for 30 day

Category
Treatment - Drugs

3

Description
Placebo group: 2 capsule 1 g (containing 30 mg starch) for 30 day
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Clinics in Tabriz University of Medical Science
Full name of responsible person
Laleh payahoo
Street address
Golgasht street, Tabriz.East Azarbayjan , health and nutrition faculty, tabriz medical science university
City
Tabriz

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice-chancellor for research of Tabriz University of Medical Sciences
Full name of responsible person
Mohammadreza Rashidi
Street address
Tabriz University Of Medical Sciences, Tabriz, East Azarbaijan, Iran
City
Tabriz
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 of Tabriz 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
Tabriz university of medical science
Full name of responsible person
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Person responsible for updating data

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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