

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 3 fatty 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

Laleh Payahoo

Position

MSc student in Nutrition

Other areas of specialty/work

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Person responsible for scientific inquiries

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Full name of responsible person

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Assistant professor in Nutrition

Other areas of specialty/work

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Person responsible for updating data

Contact

Name of organization / entity

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Full name of responsible person

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Position

MSc student in Nutrition

Other areas of specialty/work

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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