

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

The effect of Zinc Sulfate on Insulin resistance indices, Apo lipoproteins, Oxidative stress and inflammatory factors in obese children

Protocol summary

Summary

This triple masked crossover clinical trial comprised 60 prepubescent obese children, either female or male and aged 6-10 years. They were randomly selected from among children referred to the Pediatric Obesity & Metabolic Syndrome Clinic of the Pediatric Preventive Cardiology, Isfahan Cardiovascular Research Center, Isfahan University of Medical Sciences. The objective of study was to determine the probable therapeutic features of zinc supplementation on metabolic syndrome profiles and markers of inflammation and oxidation. Firstly, demographic data as well as weight, height, waist circumference and blood pressure were registered in questionnaire for each patient. Fasting blood samples were taken from patients and were analyzed for serum zinc, fasting blood sugar, insulin level, lipid profile, apolipoproteins A & B, leptin, malonyl dialdehyde and CRP. Then, children were randomized into two groups of equal number. For a period of 8 weeks, Group A received 20 mg Zinc Sulfate tablets and Group B took placebo. Drug and placebo were delivered in similar shapes and packs. After two months, we provided another blood exam of patients to detect changes. Following a 4-week wash out period, placebo and zinc replaced between groups, in other word, group A took placebo and group B received zinc tablets. In addition to baseline study, physical examination and biochemical tests were repeated at all stages of the trial and were analyzed to verify the authenticity of our hypothesis.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT138808061434N2**

Registration date: **2009-12-29, 1388/10/08**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2009-12-29, 1388/10/08

Registrant information

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Name of organization / entity

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Recruitment status

Recruitment complete

Funding source

Vice-chancellery for Research, Isfahan University of Medical Sciences

Expected recruitment start date

2008-01-01, 1386/10/11

Expected recruitment end date

2009-01-01, 1387/10/12

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of Zinc Sulfate on Insulin resistance indices, Apo lipoproteins, Oxidative stress and inflammatory factors in obese children

Public title

Recommending Zinc Sulfate supplement as a new treatment approach in obese children to improve

metabolic profiles (such as LDL, HDL, blood sugar) in plasma

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: underwriting consent form by one of parents or legal guardian, simple obesity, pre-pubertal stage, no underlying health disorder
Exclusion criteria: Possible drug side effects, no compliance for follow up

Age

From **6 years** old to **10 years** old

Gender

Both

Phase

1-2

Groups that have been masked

No information

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Triple blinded

Blinding description

Placebo

Used

Assignment

Crossover

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Isfahan Cardiovascular Research Center, Isfahan
University of Medical Sciences

Street address

Khorram St., Isfahan, Iran

City

Isfahan

Postal code

Approval date

2007-08-10, 1386/05/19

Ethics committee reference number

86112

Health conditions studied

1

Description of health condition studied

Metabolic Syndrome

ICD-10 code

E78.8

ICD-10 code description

Other disorders of lipoprotein metabolism

Primary outcomes

1

Description

Waist circumference

Timepoint

At the beginning, 2nd month and 5th month of study

Method of measurement

Non elastic tape with accuracy of 0.1 cm

2

Description

Weight

Timepoint

At the beginning, 2nd month and 5th month of study

Method of measurement

SECA medical scale with the accuracy of 0.1 kg

3

Description

Height

Timepoint

At the beginning of study

Method of measurement

SECA stadiometer with the accuracy of 0.1 cm

4

Description

Blood pressure

Timepoint

At the beginning, 2nd month and 5th month of study

Method of measurement

Mercury sphygmomanometer with the accuracy of 1mmHg

5

Description

High-density lipoprotein (HDL)

Timepoint

At the beginning, 2nd month and 5th month of study

Method of measurement

Enzymatic

6

Description

Triglycerides(TG)

Timepoint

At the beginning, 2nd month and 5th month of study

Method of measurement

Enzymatic

7

Description

Fasting Blood Sugar(FBS)

Timepoint

At the beginning, 2nd month and 5th month of study

Method of measurement

Glucose Oxidase method

8

Description

Zinc level of plasma

Timepoint

At the beginning, 2nd month and 5th month of study

Method of measurement

ELISA

Secondary outcomes

1

Description

Total cholesterol

Timepoint

At the beginning, 2nd month and 5th month of study

Method of measurement

Enzymatic

2

Description

Low Density Lipoprotein(LDL)

Timepoint

At the beginning, 2nd month and 5th month of study

Method of measurement

Directly

3

Description

Fasting Insulin

Timepoint

At the beginning, 2nd month and 5th month of study

Method of measurement

ELISA

4

Description

HOMA-IR

Timepoint

At the beginning, 2nd month and 5th month of study

Method of measurement

calculation

5

Description

hs-CRP

Timepoint

At the beginning, 2nd month and 5th month of study

Method of measurement

Immunoturbidimetry

6

Description

Leptin

Timepoint

At the beginning, 2nd month and 5th month of study

Method of measurement

serum

7

Description

Malonyl dialdehyd

Timepoint

At the beginning, 2nd month and 5th month of study

Method of measurement

Serum

8

Description

APOA

Timepoint

At the beginning, 2nd month and 5th month of study

Method of measurement

ELISA

9

Description

APOB

Timepoint

At the beginning, 2nd month and 5th month of study

Method of measurement

ELISA

Intervention groups

1

Description

Placebo capsule once daily for 2 months

Category

Placebo

2

Description

Zinc Sulfate tablet (containing 20 mg Zinc element) once daily for 2 months

Category

empty

Recruitment centers

1

Recruitment center

Name of recruitment center

Isfahan Cardiovascular Research Center and Isfahan Endocrine & Metabolism Research Center, Isfahan U

Full name of responsible person

Roya Kelishadi, MD

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Web page address**Sponsors / Funding sources****1****Sponsor****Name of organization / entity**Vice Chancellery for Research, Isfahan University of
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Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding sourceVice Chancellery for Research, Isfahan 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**Isfahan Cardiovascular Research Center, Isfahan
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empty
Analytic Code
empty

Data Dictionary
empty