Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 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

Name
Roya Kelishadi
Name of organization / entity
Isfahan University of Medical Sciences
Country
Iran (Islamic Republic of)
Phone
+98 31 1792 3060
Email address
kelishadi@med.mui.ac.ir

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 o.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 dialdehid
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

Street address
Khorram St.
City
Isfahan

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice Chancellery for Research, Isfahan University of Medical Sciences
Full name of responsible person
Peyman Adibi, MD
Street address
Hezar Jarib St.
City
Isfahan
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Vice 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 University of Medical Sciences
Full name of responsible person
Roya Kelishadi
Position
Associate Professor
Other areas of specialty/work
Street address
Khorram St.
City
Isfahan
Postal code
Phone
+98 31 1337 7881
Fax
+98 31 1337 3435
Email
kelishadi@med.mui.ac.ir
Web page address
www.crc.mui.ac.ir

Person responsible for scientific inquiries

Contact
Name of organization / entity
Isfahan Cardiovascular Research Center, Isfahan University of Medical Sciences
Full name of responsible person
Roya Kelishadi
Position
Associate Professor
Other areas of specialty/work
Street address
Khoram st., Isfahan, Iran
City
Isfahan
Postal code
Phone
+98 31 1337 7881
Fax
Email
kelishadi@med.mui.ac.ir
Web page address

Person responsible for updating data

Contact
Name of organization / entity
Isfahan Cardiovascular Research Center, Isfahan University of Medical Sciences
Full name of responsible person
Roya Kelishadi, MD
Position
Md, Associate Professor
Other areas of specialty/work
Street address
Sedigheh Tahereh Treatment and Research Complex,Khorram St.,Isfahan,Iran
City
Isfahan
Postal code
Phone
+98 31 1335 9090
Fax
+98 311373435
Email
kelishadi@med.mui.ac.ir
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