Clinical Trial Protocol
Iranian Registry of Clinical Trials

19 Jun 2026

The effects of zinc supplementation compared with placebo on ultrasound findings and metabolic profiles in obese children and adolescents with nonalcoholic fatty liver disease

Protocol summary

Study aim

Objective: The aim of this study is to determine the effects of zinc supplementation on on ultrasound findings and metabolic profiles in obese children and adolescents with nonalcoholic fatty liver disease.

Design

Study design: Randomized double-blind placebo-controlled trial. Patients will be assigned into two groups to receive zinc supplement (n=30) or placebo (n=30).

Settings and conduct

Among obese children and adolescents with nonalcoholic fatty liver disease referred to Pediatric Clinic of Shahid Beheshti Hospital affiliated to Kashan University of Medical Sciences, 60 patients will be selected according to inclusion and exclusion criteria. Participants, investigators or the assessors of the outcomes are unaware of the study groups. Supplements and placebos are similar in shape and size. Fasting blood samples will be taken at baseline and 16 weeks after the intervention. At the beginning and the end of the intervention: 16 weeks.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Obese children and adolescents with nonalcoholic fatty liver disease aged 10 to 18 years old. Exclusion criteria: Taking any antioxidant and/or anti-inflammatory supplements within 3 months prior to the enrollment, patients with infectious and autoimmune diseases, hypersensitivity to the study medication, and unwillingness to cooperate.

Intervention groups

Intervention group: 30 mg elemental zinc (Donyaye Behdasht, Tehran, Iran) daily for 16 weeks orally. Control group: Placebo (Donyaye Behdasht, Tehran, Iran), daily for 16 weeks orally.

Main outcome variables

Outcomes: hs-CRP (primary outcome) and ultrasound findings, serum liver enzymes, and lipid profiles (secondary outcomes) will be quantified at study baseline and end-of-trial.

General information

Reason for update

The updating process was done before publishing the paper to correct the registration information.

Acronym

IRCT registration information

IRCT registration number: **IRCT20200531047614N1**
Registration date: **2020-06-19, 1399/03/30**
Registration timing: **registered_while_recruiting**

Last update: **2022-10-15, 1401/07/23**
Update count: **2**

Registration date

2020-06-19, 1399/03/30

Registrant information

Name
Mohammad Rajabi
Name of organization / entity
Country
Iran (Islamic Republic of)
Phone
+98 31 5554 0026
Email address
rajabi-m@kaums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-05-21, 1399/03/01

Expected recruitment end date

2021-12-28, 1400/10/07

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effects of zinc supplementation compared with placebo on ultrasound findings and metabolic profiles in obese children and adolescents with nonalcoholic fatty liver disease

Public title

Zinc supplementation in treatment of obese children and adolescents with nonalcoholic fatty liver disease

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Obese children and adolescents diagnosed with nonalcoholic fatty liver Patients aged 10-18 years old.

Exclusion criteria:

Taking any antioxidant and/or anti-inflammatory supplements within 3 months prior to the enrollment. Patients with infectious and autoimmune diseases Hypersensitivity to the study medication. Unwillingness to cooperate

Age

From **10 years** old to **18 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

Patients will be randomly assigned into two groups. A randomization list will be generated from 1 to 60 by a random number generator (https://stattrek.com/statistics/random-number-generator.aspx) and patients were randomly assigned into each intervention group by their numbers. The block randomization technique with 1:1 ratio will be used to achieve balanced group sizes.

Blinding (investigator's opinion)

Double blinded

Blinding description

Randomization and allocation will be concealed from the researchers and participants until the final analyses are completed. Another person at the Pediatric clinic of Shahid Beheshti Hospital, affiliated to Kashan University of Medical Science, who is not involved in the trial and not aware of random sequences, will assign the participants to intervention groups. Supplements and placebos are in the same packaging at the Donyaye Behdasht Pharmaceutical company. Only the code is written on the packages. Patients, parents and researchers will not know the type of intervention. After analyzing the data, pocket codes will be decoded. Children, their parents, investigators or the assessors of the outcomes are unaware of the study groups.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Kashan University of Medical Sciences

Street address

Ghotbe Ravandi Boulevard, Kashan

City

Kashan

Province

Isfehan

Postal code

8115187159

Approval date

2020-05-18, 1399/02/29

Ethics committee reference number

IR.KAUMS.MEDNT.REC.1399.007

Health conditions studied

1

Description of health condition studied

Non alcoholic fatty liver disease (NAFLD)

ICD-10 code

K75.81

ICD-10 code description

Nonalcoholic steatohepatitis (NASH)

Primary outcomes

1

Description

Hs-CRP

Timepoint

At the beginning of the study and after 16 weeks of intervention

Method of measurement

Elisa kit

Secondary outcomes

1

Description
Severity of liver steatosis
Timepoint
At the beginning of the study and after 16 weeks of intervention
Method of measurement
Sonography

2

Description
serum liver enzymes
Timepoint
At the beginning of the study and after 16 weeks of intervention
Method of measurement
Enzymatic kit

3

Description
Total cholesterol
Timepoint
At the beginning of the study and after 16 weeks of intervention
Method of measurement
Enzymatic kit

4

Description
HDL
Timepoint
At the beginning of the study and after 16 weeks of intervention
Method of measurement
Enzymatic kit

5

Description
Triglycerides
Timepoint
At the beginning of the study and after 16 weeks of intervention
Method of measurement
Enzymatic kit

6

Description
LDL
Timepoint
At the beginning of the study and after 16 weeks of intervention
Method of measurement
Enzymatic kit

Intervention groups

1

Description
Intervention group: 30 mg elemental zinc (Donyaye Behdasht, Tehran, Iran) daily for 16 weeks orally.
Category
Treatment - Drugs

2

Description
Control group: Placebo (Donyaye Behdasht, Tehran, Iran), daily for 16 weeks orally.
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Pediatric Clinic of Shahid Beheshti hospital of Kashan
Full name of responsible person
Dr. Mohammad Reza Sharif
Street address
Ghotbe Ravandi Boulevard, Kashan
City
Kashan
Province
Isfehan
Postal code
8115187159
Phone
+98 31 5562 0608
Email
banafshe-h@kaums.ac.ir

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Kashan University of Medical Sciences
Full name of responsible person
Dr. Hamidreza Banafshe
Street address
Ghotbe Ravandi Boulevard, Kashan
City
Kashan
Province
Isfehan
Postal code
8115187159
Phone
+98 31 5562 0608
Email
banafshe-h@kaums.ac.ir
Grant name

Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Kashan University of Medical Sciences
Proportion provided by this source
100
Public or private sector
Public
Domestic or foreign origin
Domestic
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
Academic

Person responsible for general inquiries

Contact
Name of organization / entity
Kashan University of Medical Sciences
Full name of responsible person
Dr. Mohammad Reza Sharif
Position
Professor
Latest degree
Subspecialist
Other areas of specialty/work
Pediatrics
Street address
Ghotbe Ravandi Boulevard, Kashan
City
Kashan
Province
Isfehan
Postal code
81151-87159
Phone
+98 31 5554 0026
Email
mrsharifmd@yahoo.com

Person responsible for scientific inquiries

Contact
Name of organization / entity
Kashan University of Medical Sciences
Full name of responsible person
Dr. Mohammad Reza Sharif
Position
Professor
Latest degree
Subspecialist
Other areas of specialty/work
Pediatrics
Street address
Ghotbe Ravandi Boulevard, Kashan
City
Kashan
Province
Isfehan
Postal code
81151-87159
Phone
+98 31 5554 0026
Email
mrsharifmd@yahoo.com

Person responsible for updating data

Contact
Name of organization / entity
Kashan University of Medical Sciences
Full name of responsible person
Dr. Mohammad Reza Sharif
Position
Professor
Latest degree
Subspecialist
Other areas of specialty/work
Pediatrics
Street address
Ghotbe Ravandi Boulevard, Kashan
City
Kashan
Province
Isfehan
Postal code
81151-87159
Phone
+98 31 5554 0026
Email
mrsharifmd@yahoo.com

Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be a plan to make this available
Study Protocol
Undecided - It is not yet known if there will be a plan to make this available
Statistical Analysis Plan
Undecided - It is not yet known if there will be a plan to make this available
Informed Consent Form
Undecided - It is not yet known if there will be a plan to make this available
Clinical Study Report
Undecided - It is not yet known if there will be a plan to make this available
Analytic Code
Undecided - It is not yet known if there will be a plan to make this available
Data Dictionary
Undecided - It is not yet known if there will be a plan to make this available