Clinical Trial Protocol
Iranian Registry of Clinical Trials

02 Nov 2026

Effect of zinc supplementation on serum zinc status, lipid profile, liver enzymes (ALT, AST), insulin resistance, inflammatory markers and oxidative stress in non-alcoholic fatty liver patients

Protocol summary

Study aim

The effect of zinc supplementation on serum zinc status, lipid profile, liver enzymes (ALT, AST), insulin resistance, inflammatory markers and oxidative stress in non-alcoholic fatty liver patients with zinc deficiency

Design

A randomized, controlled, double-blind, placebo-controlled clinical trial

Settings and conduct

Patients were referred to Imam Reza clinic after being admitted to the test and then referred to Shahid Motahari clinic for blood sampling. The patient-level study and the outcome evaluator will be blinded.

Participants/Inclusion and exclusion criteria

Inclusion criteria: -Both sex (male and female) - Ages between 18 and 70 years -Attention to fatty liver confirmed by ultrasound - Not consuming alcoholic beverages - Lack of lipodystrophy - Lack of parenteral nutrition - No diseases that affect the bile and bile ducts - No severe weight loss 6 months ago Lack of congenital metabolic diseases - Not taking medications that cause fatty liver (methotrexate, tamoxifen, valproate, etc.) -No pregnancy and lactation - Lack of serum ALT levels more than 10 times the limit - No history of severe systemic diseases such as cardiovascular disease, kidney disease - No chemotherapy for the past year - No drug or alcohol poisoning - Not taking any supplements containing zinc Exclusion criteria: - Sensitivity to intervention supplements

Intervention groups

Patients in the intervention group: Coated capsule containing 30 mg of zinc made in Nature made company Patients in the control group: The placebo will be prepared by the Faculty of Pharmacy of Shiraz University of Medical Sciences and will be identical in appearance, size, color, and so on.

Main outcome variables

Mean serum zinc; Liver enzymes (ALT, AST); Insulin resistance; hsCRP inflammatory factor; malondialdehyde; total antioxidant capacity, triglyceride, total cholesterol, HDL-cholesterol; LDL-cholesterol;

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20191015045113N1**
Registration date: **2019-12-08, 1398/09/17**
Registration timing: **retrospective**

Last update: **2019-12-08, 1398/09/17**
Update count: **0**

Registration date

2019-12-08, 1398/09/17

Registrant information

Name

Seyed Mohammad Amin Rezaei

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 74 3232 2519

Email address

seyedamin.rezaei69@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-09-23, 1397/07/01

Expected recruitment end date

2019-10-23, 1398/08/01

Actual recruitment start date

2018-09-23, 1397/07/01

Actual recruitment end date

2019-02-20, 1397/12/01

Trial completion date

2019-09-23, 1398/07/01

Scientific title

Effect of zinc supplementation on serum zinc status, lipid profile, liver enzymes (ALT, AST), insulin resistance, inflammatory markers and oxidative stress in non-alcoholic fatty liver patients

Public title

The effect of zinc supplementation on fatty liver

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

-Attention to fatty liver confirmed by ultrasound - Ages between 18 and 70 years -Not consuming alcoholic beverages - Lack of other liver diseases such as viral hepatitis, liver cirrhosis, Wilson's disease ... - Lack of parenteral nutrition -No diseases that affect the bile and bile ducts - No severe weight loss 6 months ago -Not taking medications that cause fatty liver (methotrexate, tamoxifen, valproate, etc.) -No pregnancy and breastfeeding - Lack of serum ALT levels more than 10 times the limit - No chemotherapy during the past year - Not taking any supplements containing zinc

Exclusion criteria:

People who have done chemotherapy over the past year People with any biliary disease People taking any supplements and drugs containing zinc People who have had severe weight loss in the past 6 month People taking any form of fatty liver medication

Age

From **18 years** old to **70 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Outcome assessor

Sample size

Target sample size: **50**

Actual sample size reached: **50**

Randomization (investigator's opinion)

Randomized

Randomization description

Samples were included in this study by simple randomization. In this way, patients were randomly assigned to one of the intervention and placebo groups after having met the inclusion criteria and obtaining written consent.That way the first patient in The intervention group and the next group are included in the control group.This is done until the end of the sample.

Blinding (investigator's opinion)

Double blinded

Blinding description

The patient-level study and the outcome evaluator will be blinded. Medication and placebo capsules are divided into two equal groups before filling on the basis of random number table by block method. Only a researcher based on the initial stored form of randomized results can decode the contents of each capsule. The person responsible for delivering the medication, the patient, the physician, and the outcome assessor will not be aware of the coding. The results of the intervention and control groups will be delivered to the statistical analyst under the titles of groups A and B.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Shiraz University of Medical Sciences

Street address

Bahman Beigi Boulevard, Bibi Hakime Hospital

City

shiraz

Province

Fars

Postal code

7581359560

Approval date

2019-01-22, 1397/11/02

Ethics committee reference number

IR.SUMS.REC.1397.105

Health conditions studied

1

Description of health condition studied

Non Alcoholic Fatty Liver Disease

ICD-10 code

K76.0

ICD-10 code description

Fatty (change of) liver, not elsewhere classified

Primary outcomes

1

Description

Serum zinc

Timepoint

8 weeks

Method of measurement

Blood sampling

2

Description
insulin resistance
Timepoint
8 weeks
Method of measurement
Blood sampling

3

Description
ALT
Timepoint
8 Week
Method of measurement
blood sample

Secondary outcomes

1

Description
Fasting blood sugar
Timepoint
8 week
Method of measurement
blood sample

2

Description
Serum total cholesterol
Timepoint
8 week
Method of measurement
blood sample

3

Description
Serum triglyceride
Timepoint
8 Week
Method of measurement
blood sample

4

Description
MDA
Timepoint
8 week
Method of measurement
blood sample

5

Description
Total Antioxidant Capacity (TAC)
Timepoint
8 week
Method of measurement
blood sample

6

Description
hs-CRP
Timepoint
8 week
Method of measurement
blood sample

Intervention groups

1

Description
Intervention group: Twenty - five patients with ultrasound - confirmed non - alcoholic fatty liver disease received a coated capsule containing 30 mg of Nature Made made at the Faculty of Pharmacy of Shiraz University of Medical Sciences for 8 weeks.
Category
Treatment - Drugs

2

Description
Control group: Twenty-five patients with ultrasound-approved non-alcoholic fatty liver were included for 8 weeks with a starch-coated capsule made at Shiraz University of Medical Sciences School of Pharmacy in terms of appearance, size, and color. ... with the complement of zinc they receive.
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Shahid Motahari - Imam Reza Clinic
Full name of responsible person
Seyed Mohammad Amin Rezaei
Street address
Bahman Beigi Boulevard, Bibi Hakime Hospital
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Shiraz University of Medical Sciences
Full name of responsible person
Dr. Younes Qasemi
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Email
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Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Shiraz 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

2

Sponsor
Name of organization / entity
Vice chancellor for research, Shiraz University of Medical Sciences
Full name of responsible person
Dr. Younes Qasemi
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Email
seyedamin.rezaei69@gmail.com
Grant name
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Yes
Title of funding source
Vice chancellor for research, Shiraz 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
Shiraz University of Medical Sciences
Full name of responsible person
Seyed Mohammad Amin Rezaei
Position
Student
Latest degree
Bachelor
Other areas of specialty/work
Nutrition
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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available

Study Protocol
Yes - There is 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
Yes - There is a plan to make this available

Clinical Study Report
Yes - There is a plan to make this available

Analytic Code
Yes - There is a plan to make this available

Data Dictionary
Yes - There is a plan to make this available

Title and more details about the data/document
All data is shared after unidentifiable people

When the data will become available and for how long
Start of access period 6 months after printing results

To whom data/document is available
For people working in science institutes

Under which criteria data/document could be used
For meta-analysis studies

From where data/document is obtainable
seyed mohammad amin rezaei 09177422832

What processes are involved for a request to access data/document
-The applicant can receive the file after up to one month after the call or email.

Comments