

Clinical Trial Protocol

Iranian Registry of Clinical Trials

19 Jun 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

Street address

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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

Street address

Bibi Hakimeh Hospital

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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

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 scientific inquiries

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Full name of responsible person

Seyed Mohammad Amin Rezaei

Position

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Latest degree

Bachelor

Other areas of specialty/work

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Person responsible for updating data

Contact

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Full name of responsible person
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Position
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Latest degree
Bachelor
Other areas of specialty/work
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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