

Clinical Trial Protocol

Iranian Registry of Clinical Trials

19 Jun 2026

Effect of Zinc Supplementation and dietary weight loss on oxidative stress, steatosis, liver enzymes, glycemic and lipid profile Status in Non-Alcoholic Fatty Liver disease

Protocol summary

Study aim

investigation effect of zinc supplementation on steatosis and stress oxidative status in non-alcoholic fatty liver disease patients.

Design

The study will be conducted as a double-blind clinical trial on non-alcoholic fatty liver patients

Settings and conduct

Sample selection will be done among patients referring to gastrointestinal tract after confirmation of fatty liver disease .Samples were randomly assigned to coding groups 1 and 2, respectively, into two groups of control and intervention. In the selection of samples in two groups, the matching is based on age, gender, body mass index (BMI).

Participants/Inclusion and exclusion criteria

inclusion criteria: Patients aged up to 18 years and more, an involvement of 33% of liver tissue with fats by ultrasound and BMI between 25-35 exclusion criteria: Unwillingness of patients to participate in the study, pregnancy, breastfeeding, travel , smokers, iron supplementation users), diabetic patients, alcohol consumption, patients with hepatitis B and C, hemochromatosis, Wilson's disease, patients with Heart failure, kidney, autoimmunity, hypothyroidism or hyperthyroidism, Grade3 fatty liver patients, athletes, patients with any malabsorption , Weight changes over 5 kg Within the past 3 months, follow a diet plan and certain physical activity, consumption some drugs

Intervention groups

Patients in the intervention group will receive zinc gluconate supplement for a period of three months. The control group will receive a placebo capsule

Main outcome variables

FBS, serum insulin, lipid profile, liver enzymes, steatosis

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20181005041238N1**

Registration date: **2018-12-13, 1397/09/22**

Registration timing: **registered_while_recruiting**

Last update: **2018-12-13, 1397/09/22**

Update count: **0**

Registration date

2018-12-13, 1397/09/22

Registrant information

Name

Mojdeh Fathi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 61 3337 5155

Email address

mojdeh68.fathi@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-10-23, 1397/08/01

Expected recruitment end date

2019-02-20, 1397/12/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of Zinc Supplementation and dietary weight loss on oxidative stress, steatosis, liver enzymes, glycemic and lipid profile Status in Non-Alcoholic Fatty Liver disease

Public title

zinc supplementation and non-alcoholic fatty liver disease

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

Patients aged up to 18 years and more an involvement of 33% of liver tissue with fats by ultrasound BMI between 25-35

Exclusion criteria:

An unwillingness of patients to participate in the study pregnancy breastfeeding travel for more than 2 weeks smokers iron supplementation users diabetes patients alcohol consumption patients with hepatitis B and C hemochromatosis Wilson's disease patients with heart failure kidney disease autoimmunity hypothyroidism or hyperthyroidism Grade3 fatty liver patients athletes patients with any malabsorption Weight changes over 5 kg In the last 3 months follow a diet plan and certain physical activity use of hepatotoxic drugs such as blockers, calcium channel, high doses of synthetic estrogens, methotrexate, chloroquine, tamoxifen, non-steroid anti-inflammatory drugs, amiodarone, statins and fibers consumption drugs such as cefalexin, tetracycline and its derivatives, ceftibuten, deferiprone, antibiotics Quinolone is consumed

Age

From **18 years** old

Gender

Both

Phase

0

Groups that have been masked

- Participant
- Care provider
- Outcome assessor
- Data analyser

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

Samples were randomly assigned to coding 1 and 2, respectively, into two groups of control and intervention.

Blinding (investigator's opinion)

Double blinded

Blinding description

Zinc and placebo supplements are quite similar in appearance and the clinical staff and patients do not know

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

National Committee on Ethics in Bioethics

Street address

hezarjarib

City

Isfahan

Province

Isfahan

Postal code

7311431103

Approval date

2018-11-18, 1397/08/27

Ethics committee reference number

IR.MUI.RESEARCH.REC.316.1397

Health conditions studied

1

Description of health condition studied

Nonalcoholic fatty liver

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

differences of serum insulin

Timepoint

Before the intervention begins and week12

Method of measurement

kit

2

Description

differences of fasting blood sugar

Timepoint

Before the intervention begins and Week 12

Method of measurement

kit

3

Description

differences of serum triglyceride

Timepoint

Before the intervention begins and Week 12

Method of measurement

kit

4

Description

differences of serum LDL-C

Timepoint

Before the intervention begins and Week 12

Method of measurement

kit

5

Description

differences of serum HDL-C

Timepoint

Before the intervention begins and Week 12

Method of measurement

kit

6

Description

differences of serum total cholesterol

Timepoint

Before the intervention begins and Week 12

Method of measurement

kit

7

Description

differences of serum ALT enzyme

Timepoint

Before the intervention begins and Week 12

Method of measurement

kit

8

Description

differences of serum AST enzyme

Timepoint

Before the intervention begins and Week 12

Method of measurement

kit

9

Description

differences of serum ALP

Timepoint

Before the intervention begins and Week 12

Method of measurement

kit

10

Description

differences of serum SOD1 enzyme

Timepoint

Before the intervention begins and Week 12

Method of measurement

colorimetry

11

Description

differences of serum MDA

Timepoint

Before the intervention begins and Week 12

Method of measurement

colorimetry

Secondary outcomes

1

Description

differences of BMI

Timepoint

Before the intervention begins and week6 and week12

Method of measurement

Weighing scales and meter

2

Description

differences of body fat percentage

Timepoint

Before the intervention begins and week6 and week12

Method of measurement

body stat

3

Description

differences of waist circumference

Timepoint

Before the intervention begins and week6 and week12

Method of measurement

meter

4

Description

differences of Hip circumference

Timepoint

Before the intervention begins and week6 and week12

Method of measurement

meter

Intervention groups

1

Description

Intervention group: weight loss diet and zinc gluconate(30 mg elemental-Dine) for 3 months in non-alcoholic fatty liver disease

Category

Treatment - Drugs

2

Description

Control group: weight loss diet and placebo (Dine) for 3 months in non-alcoholic fatty liver disease

Category

Other

Country of origin**Type of organization providing the funding**

Academic

Recruitment centers**1****Recruitment center****Name of recruitment center**

Gastrointestinal clinic

Full name of responsible person

Reza Amani

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kianpars Ave , west soroosh street, No 2

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Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Esfahan University of Medical Sciences

Full name of responsible personassistance of Research and Technology of Isfahan
University of Medical Sciences**Street address**

hezarjarib

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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

Esfahan 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

Person responsible for general inquiries**Contact****Name of organization / entity**

Esfahan University of Medical Sciences

Full name of responsible person

Mojdeh Fathi

Position

ph.D student

Latest degree

Master

Other areas of specialty/work

Nutrition

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Person responsible for scientific inquiries**Contact****Name of organization / entity**

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Person responsible for updating data**Contact****Name of organization / entity**

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Latest degree

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Sharing plan**Deidentified Individual Participant Data Set (IPD)**

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

analyzed data will be published

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available

Title and more details about the data/document

Full information will be published as an article

When the data will become available and for how long

23 August 2019-21 September 2019

To whom data/document is available

all person

Under which criteria data/document could be used

To cite in other studies

From where data/document is obtainable

to email address

What processes are involved for a request to access data/document

Introducing the person and the reasons for requesting documentation in the email

Comments