Clinical Trial Protocol
Iranian Registry of Clinical Trials

01 Nov 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
Isfehan

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

Recruitment centers

1

Recruitment center
Name of recruitment center
Gastrointestinal clinic
Full name of responsible person
Reza Amani
Street address
kianpars Ave , west soroosh street, No 2
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331411731
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Esfahan University of Medical Sciences
Full name of responsible person
assistance of Research and Technology of Isfahan University of Medical Sciences
Street address
hezarjarib
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7311371103
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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
Country of origin
Type of organization providing the funding
Academic

Person responsible for general inquiries

Contact
Name of organization / entity
Esfahan University of Medical Sciences
Full name of responsible person
Mojdeh Fathi
Position
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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