Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

The effect of zinc supplementation on clinical situation and biochemical markers in cirrhosis

Protocol summary

Summary

The aim of the present study was to evaluate the effects of low dose zinc supplementation on the biochemical markers and underlying disease status in cirrhotic patients. Sixty cirrhotic patients were enrolled in the double-blind, placebo-controlled, randomized clinical trial study. The exclusion criteria were age less than 18 years, hepatocellular carcinoma, use of Aldacton or other diuretics over than 50 mg daily , use of anabolic hormones, diuretics or Alb (in recent one month), sever renal or respiratory disorders, pregnancy and lactation, Diabetes Mellitus, liver transplantation during the study period and also the patients with clinical evidence of ascites. All patients in the intervention group (n=30) received long term zinc supplementation (50 mg elemental zinc sulfate daily) and the others received placebo. The Child-Pugh score and biochemical markers were assessed for both intervention and control groups at the first day and the end of 90th day intervention period. A per-protocol analysis was performed after excluding all participants who did not receive or complete the randomized intervention.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201106122017N4**
Registration date: **2011-09-07, 1390/06/16**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2011-09-07, 1390/06/16

Registrant information

Name

Alireza Ostadrahimi

Name of organization / entity

Tabriz University of Medical Sciences

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Recruitment status

Recruitment complete

Funding source

Liver and Gastrointestinal Diseases Research Center, Tabriz University of Medical Sciences

Expected recruitment start date

2006-05-05, 1385/02/15

Expected recruitment end date

2006-11-06, 1385/08/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of zinc supplementation on clinical situation and biochemical markers in cirrhosis

Public title

Zinc supplementation in cirrhotic patients

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:age more than 18 years and suffering from cirrhosis. Exclusion criteria: hepato cellular carcinoma; use of Aldacton or other diuretics over than 50 mg daily; use of anabolic hormones; diuretics or Alb (in recent one month); sever renal or respiratory disorders; pregnancy and lactation; Diabetes mellitus;

liver transplantation during the study period and patients with clinical evidence of ascites

Age

To **75 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Tabriz University of Medical Science

Street address

vice-chancellor for reseach Tabriz University of Medical Science,gholghasht Ave.

City

Tabriz

Postal code

Approval date

2005-11-12, 1384/08/21

Ethics committee reference number

8544

Health conditions studied

1

Description of health condition studied

Chronic Liver Failure

ICD-10 code

K72.1

ICD-10 code description

Chronic hepatic failure

Primary outcomes

1

Description

Child-Pugh score

Timepoint

At the first day and the end of 90th day of interventional period

Method of measurement

Numeral, calculates with severity of Ascitis, total bilirubin, INR, albumin , severity of Encephalopathy

2

Description

Serum Zinc level

Timepoint

At the first day and the end of 90th day of interventional period

Method of measurement

µg/dl

3

Description

Copper level

Timepoint

At the first day and the end of 90th day of interventional period

Method of measurement

µg/dl

4

Description

Iron level

Timepoint

At the first day and the end of 90th day of interventional period

Method of measurement

µg/dl

5

Description

Albumin level

Timepoint

At the first day and the end of 90th day of interventional period

Method of measurement

gr/dl

6

Description

BUN

Timepoint

At the first day and the end of 90th day of interventional period

Method of measurement

mg/dl

7

Description

Creatinin

Timepoint

At the first day and the end of 90th day of interventional period

Method of measurement

mg/dl

Secondary outcomes

1

Description

Clinical and lab test

Timepoint

Three month after intervention

Method of measurement

Clinical and laboratory tests

Intervention groups

1

Description

Interventional group: Zinc Sulfate Capsule , 50 mg daily, oral for three months

Category

Treatment - Drugs

2

Description

The control group: starch coated Capsule, daily for three months

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Sheikhorrais speciality and subspeciality clinic

Full name of responsible person

Mohammad Hossein Somi, MD

Street address

Azadi Ave.

City

Tabriz

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Liver and Gastrointestinal Diseases Research Center, Tabriz University of Medical Sciences

Full name of responsible person

Mohammad Hossein Somi

Street address

Imam Reza Hospital, Gholghasht Ave.

City

Tabriz

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Liver and Gastrointestinal Diseases Research Center, Tabriz University of Medical Sciences

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

empty

Person responsible for general inquiries

Contact

Name of organization / entity

Liver and Gastrointestinal Diseases Research Center, Tabriz University of Medical Sciences

Full name of responsible person

Parisa Rezaeifar, MD

Position

Resident of Internal Medicine

Other areas of specialty/work

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Person responsible for scientific inquiries

Contact

Name of organization / entity

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Full name of responsible person

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Other areas of specialty/work

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Person responsible for updating data

Contact
Name of organization / entity
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Parisa Rezaeifar, MD
Position
resident of Internal medicine
Other areas of specialty/work
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Tabriz
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Fax
Email
Web page address

Sharing plan

Deidentified Individual Participant Data Set (IPD)
empty
Study Protocol
empty
Statistical Analysis Plan
empty
Informed Consent Form
empty
Clinical Study Report
empty
Analytic Code
empty
Data Dictionary
empty