

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

09 Jun 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

##### Country

Iran (Islamic Republic of)

##### Phone

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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 research 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 Ascites, 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**  
Sheikhorrails 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

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Liver and Gastrointestinal Diseases Research Center, Tabriz University of Medical Sciences  
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Alirreza Ostad Rahimi, MD  
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## Person responsible for updating data

### Contact

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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**

**Street address**

**City**

Tabriz

## 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*