

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

### Effectiveness of vitamin D supplementation on severity of cirrhosis based on CHILD and MELD scores in patients with decompensate cirrhosis

#### Protocol summary

2016-02-28, 1394/12/09

##### Summary

Purpose of the study: A single-blind, clinical trial, with block randomization design, investigating the effect of vitamin D supplementation on severity of cirrhosis based on CHILD and MELD scores in patients with decompensate cirrhosis. Study population: All chronic liver patients with CHILD>000 and MELD>000 admitted to Imam Reza Hospital due to complications. Inclusion criteria: All the decompensated cirrhosis patients (CHILD≥7) admitted to hospital or referred to Gastroenterology Clinics; aged more than 18 years; and consent to participate in the study. Exclusion criteria: Human immunodeficiency virus patients; renal failure due to reasons other than liver failure; malabsorption such as chronic diarrhea, celiac, chronic pancreatitis; patients undergoing corticosteroid treatment; pregnancy; and cirrhosis patients secondary to cholestasis such as primary biliary cirrhosis. Sample size: 80 Study intervention: 50000 units of vitamin D on a daily basis for three months. The outcome of the study: Survey of liver function based on MELD scoring system according to levels of bilirubin and creatinine serum as well as Child-Pugh classification system that classifies the severity of liver diseases into five categories, results in the two groups will be compared with the initial values after three months.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT2016020326342N1**

Registration date: **2016-02-28, 1394/12/09**

Registration timing: **prospective**

Last update:

Update count: **0**

**Registration date**

##### Registrant information

###### Name

Hossein Ali Abbasi

###### Name of organization / entity

Mashhad University of Medical Sciences

###### Country

Iran (Islamic Republic of)

###### Phone

+98 51 3854 3031

###### Email address

mozaffarih@mums.ac.ir

##### Recruitment status

###### Recruitment complete

##### Funding source

Vice Chancellor for Research, Mashhad University of Medical Sciences

##### Expected recruitment start date

2016-03-11, 1394/12/21

##### Expected recruitment end date

2017-03-11, 1395/12/21

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Effectiveness of vitamin D supplementation on severity of cirrhosis based on CHILD and MELD scores in patients with decompensate cirrhosis

##### Public title

Effectiveness of vitamin D supplementation on severity of chronic liver disease

##### Purpose

Treatment

##### Inclusion/Exclusion criteria

Inclusion criteria: All the decompensated cirrhosis patients (CHILD $\geq$ 7) admitted to hospital or referred to Gastroenterology Clinics; aged more than 18 years; and consent to participate in the study. Exclusion criteria: Human immunodeficiency virus patients; renal failure due to reasons other than liver failure; malabsorption such as chronic diarrhea, celiac, chronic pancreatitis; patients undergoing corticosteroid treatment; pregnancy; and cirrhosis patients secondary to cholestasis such as primary biliary cirrhosis

#### Age

From **18 years** old to **139 years** old

#### Gender

Both

#### Phase

2

#### Groups that have been masked

*No information*

#### Sample size

Target sample size: **80**

#### Randomization (investigator's opinion)

Randomized

#### Randomization description

#### Blinding (investigator's opinion)

Single blinded

#### Blinding description

#### Placebo

Not used

#### Assignment

Parallel

#### Other design features

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Ethics Committee of Mashhad University of Medical Sciences

##### Street address

Vice Chancellor for Research, Mashhad University of Medical Sciences, Ghoreishi building, Daneshgah Street

##### City

Mashhad

##### Postal code

#### Approval date

2015-08-21, 1394/05/30

#### Ethics committee reference number

IR.Mums.sm.REC.1394.276

## Health conditions studied

### 1

#### Description of health condition studied

Chronic liver disease

#### ICD-10 code

K76.1

#### ICD-10 code description

Chronic passive congestion of liver

## Primary outcomes

### 1

#### Description

Liver function

#### Timepoint

3 months after intervention

#### Method of measurement

MELD scoring system; according to levels of bilirubin and creatinine serum

## Secondary outcomes

### 1

#### Description

Liver function

#### Timepoint

3 months after intervention

#### Method of measurement

Child-Pugh scoring system; classifies the severity of liver diseases into five categories

## Intervention groups

### 1

#### Description

Control group: popular drugs using for liver cirrhosis

#### Category

Treatment - Drugs

### 2

#### Description

Intervention group: popular drugs using for liver cirrhosis and 50000 units of vitamin D on a daily basis for three months

#### Category

Treatment - Drugs

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Emam Reza Hospital

##### Full name of responsible person

Hossein Ali Abbasi

##### Street address

Emam Reza Square, Ebne Sina Avenue

##### City

Mashhad

## Sponsors / Funding sources

### 1

#### Sponsor

**Name of organization / entity**

Vice Chancellor for Research, Mashhad University of Medical Sciences

**Full name of responsible person**

Mohsen Tafaghodi

**Street address**

Vice Chancellor for Research, Mashhad University of Medical Sciences, Ghoreishi building, Daneshgah Street, Mashhad

**City**

Mashhad

**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, Mashhad 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**

Mashhad University of Medical Sciences

**Full name of responsible person**

Hossein Ali Abbasi

**Position**

Gastroenterologist

**Other areas of specialty/work****Street address**

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## Person responsible for scientific inquiries

**Contact****Name of organization / entity**

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Homan Mozafari

**Position**

Assistant Professor

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## Person responsible for updating data

**Contact****Name of organization / entity**

Mashhad University of Medical Sciences

**Full name of responsible person**

Hossein Ali Abbasi

**Position**

Gastroenterologist

**Other areas of specialty/work****Street address**

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**City**

Mashhad

**Postal code****Phone**

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**Fax****Email**

hoseinabbasi1342@yahoo.com

**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*