

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Sep 2026

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

Protocol summary

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

2016-02-28, 1394/12/09

Registrant information

Name

Hossein Ali Abbasi

Name of organization / entity

Mashhad University of Medical Sciences

Country

Iran (Islamic Republic of)

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+98 51 3854 3031

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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

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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

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

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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