Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 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

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Name of organization / entity
Mashhad University of Medical Sciences
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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≥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
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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
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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