

Clinical Trial Protocol

Iranian Registry of Clinical Trials

28 Aug 2026

The effect of vitamin D3 supplementation on glycemic indices lipid profile and liver enzymes in cirrhotic patients

Protocol summary

Study aim

The effect of vitamin D3 supplementation on glycemic indices lipid profile and liver enzymes in cirrhotic patients

Design

Two Parallel group randomized Clinical Trial; double blinded

Settings and conduct

The aim of this study is to determine the effect of vitamin D supplementation on glycemic indices, lipid profile and liver enzymes in cirrhotic patients referring to Baqiyatallah Hospital. It is a double blind clinical trial . Sixty cirrhotic patients assigned randomly into two groups: 1- Vitamin D supplementation(50000 IU/ week for 12 weeks) (intervention group) and 2- placebo (control group). Before and after the intervention, weight, BMI, FBS, HbA1C, insulin, insulin resistance, serum 25OHD, cholesterol, TG, HDL, LDL, ALT and ALT will be measured.

Participants/Inclusion and exclusion criteria

Both Males and females age between 18 to 70 yrs
Confirmed cirrhosis disease Not taking vitamin D3 supplementation in last 3 months ago Not drinking alcohol in last 3 months ago Not having the history of gastroplasty and jajenostomy

Intervention groups

The cirrhotic patients

Main outcome variables

BMI 25 Hydroxy vitamin D3 FBS Hb A1C Insulin Insulin resistance Total cholesterol Total triglyceride LDL cholesterol HDL cholesterol AST ALT

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20140502017522N2**

Registration date: **2018-11-14, 1397/08/23**

Registration timing: **prospective**

Last update: **2018-11-14, 1397/08/23**

Update count: **0**

Registration date

2018-11-14, 1397/08/23

Registrant information

Name

Maryam Taghdir

Name of organization / entity

Baqiyatallah University of medical sciences

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-04-21, 1398/02/01

Expected recruitment end date

2019-10-23, 1398/08/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of vitamin D3 supplementation on glycemic indices lipid profile and liver enzymes in cirrhotic patients

Public title

The effect of vitamin D3 supplementation on glycemic

indices lipid profile and liver enzymes in cirrhotic patients

Purpose
Supportive

Inclusion/Exclusion criteria
Inclusion criteria:
cirrhotic patients
Exclusion criteria:
Taking vitamin D since Last 3 months Pregnant women lactating Women Patient with a history of Gastroplastic or jejunostomic vitamin D level higher than 50 ng/ml

Age
From **18 years** old to **70 years** old

Gender
Both

Phase
3

Groups that have been masked

- Participant
- Investigator

Sample size
Target sample size: **60**
Actual sample size reached: **24**
Randomization (investigator's opinion)
Randomized

Randomization description
simple randomization;
Blinding (investigator's opinion)
Double blinded

Blinding description
Patients and researchers

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Baqiyatallah University of Medical Sciences
Street address
Hospital, Mollasadra Avenue, Tehran, Iran
City
Tehran
Province
Tehran
Postal code
1435916471
Approval date
2018-10-08, 1397/07/16
Ethics committee reference number
IR.BMSU.REC.1397.039

Health conditions studied

1

Description of health condition studied
Cirrhosis
ICD-10 code
K74
ICD-10 code description
Fibrosis and cirrhosis of liver

Primary outcomes

1

Description
Body mass index (BMI)
Timepoint
Two times: 1) before supplementation 2)After 12 weeks
Method of measurement
BMI compares weight to height, and is calculated by dividing weight (in kilograms) by height (in metres squared)

2

Description
25 hydroxy vitamin D3
Timepoint
Two times: 1) before supplementation 2)After 12 weeks
Method of measurement
Units are ng / ml using 25OHD ALIZA

3

Description
Fasting blood sugar (FBS)
Timepoint
Two times: 1) before supplementation 2)After 12 weeks
Method of measurement
Units are mg / dl using autoanalyzer

4

Description
HbA1c
Timepoint
Two times: 1) before supplementation 2)After 12 weeks
Method of measurement
Units are % using HbA1c kits

5

Description
Insulin
Timepoint
Two times: 1) before supplementation 2)After 12 weeks
Method of measurement
Units are μ U / ml using insulin kits

6

Description

Insulin Resistance
Timepoint
Two times: 1) before supplementation 2) After 12 weeks
Method of measurement
Using the index, HOMA-ir

7

Description
Cholesterol
Timepoint
Two times: 1) Before of supplementation 2) after 12 weeks
Method of measurement
In mg/dl and by autoanalyzer

8

Description
Triglycerides
Timepoint
Two times: 1) Before of supplementation 2) after 12 weeks
Method of measurement
In mg/dl and by autoanalyzer

9

Description
High Density Lipoprotein
Timepoint
Two times: 1) Before of supplementation 2) after 12 weeks
Method of measurement
In mg/dl and by autoanalyzer

10

Description
Low Density Lipoprotein
Timepoint
Two times: 1) Before of supplementation 2) after 12 weeks
Method of measurement
In mg/dl and by auto analyzer

11

Description
Aspartat Amino Teransferase (AST)
Timepoint
Two times: 1) Before of supplementation 2) after 12 weeks
Method of measurement
In unit per liter and by autoanalyzer

12

Description
ALanin Amino Teransferase (AST)
Timepoint
Two times: 1) Before of supplementation 2) after 12 weeks
Method of measurement
in Unit per liter and by Autoanalyser

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: 50000 IU Vitamin D weekly for 12 weeks
Category
Treatment - Drugs

2

Description
Control group: one placebo weekly for 12 weeks
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Baqiyatallah Hospital
Full name of responsible person
Dr. Maryam Taghdir
Street address
Baghiatallah Hospital, Mollasadra Avenue, Tehran, Iran
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Bagheiat-allah University of Medical Sciences
Full name of responsible person
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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

Bagheiat-allah University of Medical Sciences

Proportion provided by this source

100

Public or private sector

Public

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

Academic

Person responsible for general inquiries

Contact

Name of organization / entity

Bagheiat-allah University of Medical Sciences

Full name of responsible person

Seyedeh Roghayeh Derogar Kasmaei

Position

MSc Student

Latest degree

Bachelor

Other areas of specialty/work

Nutrition

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Person responsible for scientific inquiries

Contact

Name of organization / entity

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Position

Assistant professor

Latest degree

Ph.D.

Other areas of specialty/work

Nutrition

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Person responsible for updating data

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Latest degree

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Other areas of specialty/work

Nutrition

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

There is no further information

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

No - There is not a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to

make this available

Data Dictionary
Not applicable