Clinical Trial Protocol
Iranian Registry of Clinical Trials

02 Nov 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

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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

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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
Twoo 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 µIU / 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)Befor of supplementation 2)after 12 weeks

Method of measurement

In mg/dl and by autoanalyzer

8

Description

Triglycerides

Timepoint

Two times:1)Befor of supplementation 2)after 12 weeks

Method of measurement

In mg/dl and by autoanalyzer

9

Description

High Density Lipoprotein

Timepoint

Two times:1)Befor of supplementation 2)after 12 weeks

Method of measurement

In mg/dl and by autoanalyzer

10

Description

Low Density Lipoprotein

Timepoint

Two times:1)Befor 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)Befor 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)Befor 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

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Baghiatallah Hospital, Mollasadra Avenue, Tehran, Iran

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

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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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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