Clinical Trial Protocol
Iranian Registry of Clinical Trials

29 May 2026

The effect of vitamin D supplementation on serum Liver enzymes in patients with Non-Alcoholic Fatty Liver Disease

Protocol summary

Summary

The purpose of this study is to evaluate the effect of vitamin D deficiency therapy on enzymatic activity in patients with nonalcoholic fatty liver. Major inclusion criteria and exclusion criteria: inclusion criteria include patients who have been referred to the gastroenterology clinic with increased liver enzymes and have been diagnosed with non-alcoholic fatty liver by surveys and sonography findings, patients with vitamin D levels below 30 ng/ml, Exclusion criteria include drug abuse, the use of vitamins (multivitamin, vitamin C and vitamin D) in the last 6 months and during the study, weight loss is more than 5% within 6 months before entering the study. Design: This study was designed as a randomized, Single-blind clinical trials. In this study, 80 patients with non-alcoholic fatty liver after completing the consent form will be included in the study and randomly (randomized block method) divided into 2 groups. Interventions: Intervention group: Patients will receive 50000 IU Pearl vitamin D3 once a week for a period of 12 weeks and will also provide recommendations for improving their lifestyle through regular exercise and setting a daily diet plan (Low Fat and Low Carb) and The control group will receive only lifestyle modification program (regular exercise and diet planning). Patients will be followed up for 12 weeks. Main outcome variables: Primary outcome variables: Serum levels of hepatic enzymes including alanine aminotransferase and aspartate aminotransferase and secondary outcome variables: weight of patients, lipid profiles and vitamin D3 levels

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2017102218124N5**
Registration date: **2017-11-20, 1396/08/29**
Registration timing: **prospective**
Last update:
Update count: **0**

Registration date

2017-11-20, 1396/08/29

Registrant information

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Name of organization / entity

Metabolic Diseases Research Center, Qazvin University of Medical Sciences

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Recruitment status

Recruitment complete

Funding source

Vice Chancellor for research of Qazvin University of Medical Sciences

Expected recruitment start date

2017-11-21, 1396/08/30

Expected recruitment end date

2018-03-11, 1396/12/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of vitamin D supplementation on serum Liver enzymes in patients with Non-Alcoholic Fatty Liver Disease

Public title

The effect of vitamin D deficiency treatment on the

improvement of patients with fatty liver disease

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion Criteria: Older than 12 years of age; high levels of liver enzymes over the past six months (ALT > 40 U/L); serum vitamin D3 level less than 30 ng/ml; diagnosis to have nonalcoholic fatty liver disease confirmed with sonography results; having non-alcoholic fatty liver disease (NAFLD) and rule out of other hepatic-enzymes rising causes such as viral and autoimmune hepatitis and other chronic liver diseases such as hereditary hemochromatosis, Wilson's disease, an α1-Antitripsin enzyme deficiency; pharmaceutical Hepatitis; consumption of Alcohol. Exclusion Criteria: Pregnancy or lactation; drug abuse; the use of vitamins (multivitamin, vitamin C and vitamin D) in the last 6 months and during the study; weight loss more than 5% during the 6 months before entering the study; diabetes; use of anti-obesity drugs; hypercalcemia; chronic kidney disease; cardio-pulmonary disease; hyperlipidemia which needs medications and Drugs; malignant history; history of the use of effective drugs on the level of ALT such as Valproic acid, Tamoxifen, HMG-COA reductase inhibitors; chemotherapy compounds; Metformin; Statins; Azathioprine; Acetaminophen; antibiotics such as Sulfanamide and Penicillins; Amiodaron; Methotrexate; Isoniazid; Steroids; herbal Medicines; Ursodeoxycholic acid at 3 months before.

Age

No age limit

Gender

Both

Phase

N/A

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

Ethical Comitte of Qazvin University of Medical Sciences

Street address

Shahid Bahonar Blvd, Qazvin.

City

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Postal code

3419759811

Approval date

2017-04-18, 1396/01/29

Ethics committee reference number

IR.QUMS.REC.1396.5

Health conditions studied

1

Description of health condition studied

Nonalcoholic fatty liver disease

ICD-10 code

K75.8

ICD-10 code description

Other specified inflammatory liver diseases

Primary outcomes

1

Description

hepatic enzymes (aminotransferase)

Timepoint

At the beginning of the study and 12 weeks after the intervention

Method of measurement

Measuring the activity of enzymes in serum

Secondary outcomes

1

Description

Lipid profiles

Timepoint

At the beginning of the study and 12 weeks after the intervention

Method of measurement

Biochemical method

2

Description

Serum level of vitamin D3

Timepoint

At the beginning of the study and 12 weeks after the intervention

Method of measurement

RadioImmuno Assay method

Intervention groups

1

Description
Intervention group: Patients will receive 50000 IU Pearl vitamin D3 once a week for a period of 12 weeks and will also provide recommendations for improving their lifestyle through regular exercise and setting a daily diet plan (Low Fat and Low Carb).

Category
Treatment - Drugs

2

Description
The control group will receive only lifestyle modification program (regular exercise and diet planning)

Category
Other

Recruitment centers

1

Recruitment center

Name of recruitment center
Velayat educational and treatment center

Full name of responsible person
Dr. Aliakbar Hajiaghamohammadi

Street address

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Vice Chancellor for research of Qazvin University of Medical Sciences

Full name of responsible person
Dr. Amir Peymani

Street address
Qazvin, Shahid Bahonar Blvd.

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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 of Qazvin 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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Full name of responsible person
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Position
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Person responsible for scientific inquiries

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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