

# 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

###### Name

Ali Akbar Hajiaghamohammadi

###### Name of organization / entity

Metabolic Diseases Research Center, Qazvin  
University of Medical Sciences

###### Country

Iran (Islamic Republic of)

###### Phone

+98 28 3336 0084

###### Email address

ahmohammadi@qums.ac.ir

##### 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  $\alpha$ 1-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

Qazvin

## 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

Radiolmmuno 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

#### City

Qazvin

## 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.

#### City

Qazvin

### 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

Qazvin University of Medical Sciences

#### Full name of responsible person

Dr. Naser Qaeme

#### Position

Assistant of Internal Medicine

#### Other areas of specialty/work

#### Street address

Velayat Hospital, Minoodar area, 22 Bahaman Blvd, Taavon Sq, Qazvin

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## Person responsible for scientific inquiries

### Contact

#### Name of organization / entity

Qazvin University Of Medical Sciences

#### Full name of responsible person

Dr. Aliakbar Hajiaghamohammadi

#### Position

Associate Professor of Gastroenterology

#### Other areas of specialty/work

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## Person responsible for updating data

### Contact

#### Name of organization / entity

Qazvin University of Medical Sciences

#### Full name of responsible person

Dr. Naser Qaeme

#### Position

Assistant of Internal Medicine

#### Other areas of specialty/work

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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*