Clinical Trial Protocol
Iranian Registry of Clinical Trials

03 Nov 2026

Effect of vitamin D supplementation on inflammatory markers, liver function, lipid profile, body composition, and sonographic findings in patients with NAFLD

Protocol summary

Summary

Vitamin D is a fat-soluble molecule that is essential for calcium balance and bone. Prevalence of vitamin D deficiency in adults is about 5 to 30 percent. But this deficiency in patients with metabolic syndrome by about 75 percent. Nonalcoholic fatty liver pathological accumulation of fat in the liver in which there is no liver disease. The prevalence of the disease around the world is estimated at 10-35% in adults. Iran is estimated that 7% of children and 35 percent of adults are infected with non-alcoholic fatty liver Nonalcoholic fatty liver is one of the components of metabolic syndrome. Studies of serum vitamin D levels associated with fatty liver there. According to the studies on the effect of vitamin D supplementation in patients with NAFLD has been.The objective of this study was to determine the effect of vitamin D supplementation on the recovery and improve the fat accumulation in the liver after liver enzymes in individuals with liver disease is ultrasound. This would be a parallel trial in which patients initially diagnosed with non-alcoholic fatty liver gastroenterologist are enrolled.Patients with NAFLD are not intervening in terms of age, sex and BMI matched with the experimental group are. In all patients, serum levels of vitamin D and liver function will be investigated.Vitamin D supplementation in the intervention group and the control group is given a placebo intervention. After 10 weeks, subjects of vitamin D levels and NAFLD are investigated.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2013060411763N8**
Registration date: **2013-09-12, 1392/06/21**
Registration timing: **retrospective**
Last update:
Update count: **0**

Registration date

2013-09-12, 1392/06/21

Registrant information

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Name of organization / entity

Isfahan University of Medical Sciences

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Recruitment status

Recruitment complete

Funding source

Isfahan University of Medical Sciences

Expected recruitment start date

2012-06-20, 1391/03/31

Expected recruitment end date

2012-09-22, 1391/07/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of vitamin D supplementation on inflammatory markers, liver function, lipid profile, body composition, and sonographic findings in patients with NAFLD

Public title

Effect of vitamin D supplementation on inflammatory

markers, liver function, lipid profile, body composition, and sonographic findings in patients with NAFLD

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria were stable increases in AST and ALT greater than 50 U / L and metabolic syndrome, which includes waist circumference greater than 40 inches for men and greater than 35 inches for women, Triglycerides greater than or equal to 150 mg /dl, HDL less than 40 mg / dl for men and less than 50 mg/dl for women, Blood pressure greater than or equal to 85/135 mmHg, fasting blood glucose greater than or equal to 110 mg / dl. The participants in this study have not hepatitis C, B and Wilson disease and no history of chronic liver disease, a disease that affects the gallbladder and bile ducts. The absence of gestational, diabetes mellitus type 1 and 2, use of drugs affecting the levels of ALT (valproic acid, tamoxifen, HMG-COA reductase inhibitors, metformin, ACE 1 and ACER 1). They do not follow the diet and weight loss because weight loss effective vitamin d. Exclusion criteria included hospitalization, lack of cooperation in the study and with an acute illness.

Age
No age limit

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **60**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Single blinded

Blinding description

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
isfahan university medical science

Street address
isfahan

City
isfahan

Postal code
8174673461

Approval date
2012-06-09, 1391/03/20

Ethics committee reference number
391214

Health conditions studied

1

Description of health condition studied
non alcohlic fatty liver disease

ICD-10 code
k76

ICD-10 code description
Other diseases of liver

Primary outcomes

1

Description
The severity of fatty liver using abdominal ultrasound at baseline and end of study

Timepoint
Baseline and 10 weeks after intervention

Method of measurement
ultrasound

2

Description
AST and ALT liver enzymes

Timepoint
Baseline and 10 weeks after intervention

Method of measurement
Blood tests

Secondary outcomes

1

Description
body composition

Timepoint
baseline and 10 weeks after intervention

Method of measurement
instrument body composition

2

Description
FBS

Timepoint
baseline and 10 weeks after intervention

Method of measurement
blood test

3

Description
lipid profile

Timepoint

baseline and 10 weeks after intervention

Method of measurement

blood test

4

Description

CRP

Timepoint

baseline and 10 weeks after intervention

Method of measurement

blood test

Intervention groups

1

Description

This randomized clinical trial will be conducted in parallel. The objective of this study is the low number of participants in this study, 60 patients with NAFLD are referred to the Medical Research Center for Gastroenterology.The consent of the individuals participating in the study will be made in the experimental group during the 10-week study, which included a week Pearl vitamin D supplements are vitamin D 50,000 IU receive.The control group during the 10 weeks, each week placebo in terms of shape, color is similar to vitamin D supplements. The study followed patients for vitamin D supplement use,Weekly basis with the individuals contacted by telephone and SMS reminders to be a supplement to these people. To assess the level of acceptance of 25-hydroxy vitamin D supplements Gyy the size of the trucks will be used to study

Category

Treatment - Drugs

2

Description

Palcebo

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

clinic fatty liver

Full name of responsible person

mahdi forroughi

Street address

City

ifahan

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Food Security Research Center

Full name of responsible person

Dr askari

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sfahan University of Medical Sciences, School Nutrition, Research Center on Food Security

City

isfahan

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Food Security Research Center

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

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food security research center

Full name of responsible person

mahdi foroughi

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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