

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Sep 2026

The effect of vitamin D supplementation on serum hepatic enzymes, oxidative stress indicators & inflammatory markers in patients with Non-Alcoholic Fatty Liver Disease: A Randomized Controlled trial

Protocol summary

Summary

The aim of study is evaluation of the effect of vitamin D supplementation on serum hepatic enzymes, oxidative stress indicators & inflammatory markers in patients with Non-Alcoholic Fatty Liver Disease Study design is double blind placebo controlled randomized clinical trial The study sample includes 60 patients (30 in intervention and 30 in control group) diagnosed with non alcoholic fatty liver disease of both gender Inclusion Criteria : diagnosis to have non alcoholic fatty liver disease ages above 18 and serum alanine transaminase enzyme level higher than normal (> 40 U/L). Exclusion criteria: Alcohol consumption greater than 20 g per day, pregnancy, lactation, having other hepatic diseases, using hepatotoxic drugs and consumption of vitamin D, vitamin E and calcium supplementation during last 6 months. Intervention: One pearl of vitamin D supplement contains 50000 IU vitamin D will be prescribed every other week for 4 months in intervention group. One placebo contains edible paraffin will be prescribed every other week for 4 months in control group. Primary Outcomes: Serum levels of hepatic enzymes include Alanine transaminase, Aspartate transaminase and alkaline phosphatase. Secondary Outcomes: Insulin resistance, Tumor necrosis factor α , Transforming growth factor β , hs-CRP, Adiponectin, Total antioxidant capacity, Malondialdehyde, Cytokeratin-18, Lipid profile, serum level of vitamin D.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2012071810333N1**

Registration date: **2012-11-14, 1391/08/24**

Registration timing: **prospective**

Last update:

Update count: **0**

Registration date

2012-11-14, 1391/08/24

Registrant information

Name

Nasrin Sharifi

Name of organization / entity

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Ahvaz Jundishapur University of Medical Sciences

Expected recruitment start date

2012-11-21, 1391/09/01

Expected recruitment end date

2013-11-22, 1392/09/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of vitamin D supplementation on serum hepatic enzymes, oxidative stress indicators & inflammatory markers in patients with Non-Alcoholic Fatty Liver Disease: A Randomized Controlled trial

Public title

The effect of vitamin D supplementation in Non Alcoholic

Fatty Liver Disease treatment

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion Criteria: Diagnosis to have non alcoholic fatty liver disease confirmed with sonography result, ages above 18 and serum alanine transaminase enzyme level higher than normal (> 40 U/L). Diabetic patients will include who have been recently diagnosed with diabetes and not using blood glucose lowering drugs or if they consume insulin and metformin, it would pass at least 6 months from starting the treatment and during this period the dose of metformin and insulin are not changed. Exclusion criteria: Alcohol consumption greater than 20 g per day, pregnancy, lactation, diseases such as hereditary hemochromatosis, Wilson's disease, an enzyme deficiency α 1 Antitripsin, history of jejunoileal bypass surgery orgastroplasty, experience to perform the total parenteral nutrition at 6 months before, consumption of hepatotoxic drugs such as calcium channel blocker, high doses of synthetic estrogens, methotrexate, amiodarone, chloroquine, a history of hypothyroidism and Cushing's syndrome. Serum calcium greater than 10.6mg / dl , a history of kidney stones, renal failure, intake of vitamin D,vitamin E and calcium supplements during last 6 months.

Age
From **18 years** old to **75 years** old

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)
Double blinded

Blinding description

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids
empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ahvaz Jundishapur University of Medical Sciences

Street address

Deputy of research and technology, Ahvaz
Jundishapur University of Medical Sciences, Golestan

Ave, Ahvaz, Iran
City
Ahvaz
Postal code
Approval date
2012-10-27, 1391/08/06
Ethics committee reference number
ETH-605

Health conditions studied

1

Description of health condition studied

non alcoholic fatty liver disease

ICD-10 code

K76.0

ICD-10 code description

Fatty (change of) liver

Primary outcomes

1

Description

Alanine Transaminase

Timepoint

Before and after intervention

Method of measurement

U/L - Laboratory kit

2

Description

Aspartate transaminase

Timepoint

Before and after intervention

Method of measurement

U/L - Laboratory kit

3

Description

Alkaline Phosphatase

Timepoint

before and after intervention

Method of measurement

U/L - laboratory kit

Secondary outcomes

1

Description

TNF-Alpha

Timepoint

Before and after intervention

Method of measurement

Pg/ml - Laboratory kit

2

Description

Insulin Resistance

Timepoint

Before and after intervention

Method of measurement

based on HOMA-IR

3

Description

hs-CRP

Timepoint

Before and after intervention

Method of measurement

Mg/L - Laboratory kit

4

Description

Transforming Growth Factor beta (TGF-b)

Timepoint

Before and after intervention

Method of measurement

Pg/ml- Laboratory kit

5

Description

Cytokeratin-18

Timepoint

Before and after intervention

Method of measurement

U/L - Laboratory kit

6

Description

Adiponectin

Timepoint

Before and after intervention

Method of measurement

microgram/ml - laboratory kit

7

Description

Malondialdehyde

Timepoint

Before and after intervention

Method of measurement

uM/L- laboratory kit

8

Description

Total antioxidant capacity

Timepoint

Before and after intervention

Method of measurement

mM Trolox equivalent- laboratory kit

9

Description

total cholesterol

Timepoint

Before and after intervention

Method of measurement

mg/dl - laboratory kit

10

Description

Triglyceride

Timepoint

Before and after intervention

Method of measurement

mg/dl- laboratory kit

11

Description

LDL-c

Timepoint

Before and after intervention

Method of measurement

mg/dl - laboratory kit

12

Description

HDL-c

Timepoint

Before and after intervention

Method of measurement

mg/dl- laboratory kit

13

Description

Serum Vitamin D

Timepoint

Before and after intervention

Method of measurement

ng/ml - laboratory Kit

Intervention groups

1

Description

Intervention: One pearl of Vitamin D (50000 IU) every other week for 4 months.

Category

Treatment - Drugs

2

Description

Control: Placebo with similarity in physical properties to Vitamin D pearl contains edible paraffin will be prescribed one every other week for 4 months

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Ghaem Medical Clinic

Full name of responsible person

Dr. Eskandar Hajiani

Street address

Ghaem Medical Clinic, Taleghani Ave, Ahvaz, Iran

City

Ahvaz

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Ahvaz Jundishapur University of Medical Sciences

Full name of responsible person

Dr. Mohammadreza Abbaspour

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Deputy of Research and Technology-Ahvaz
Jundishapur University of Medical Sciences- Golestan
Ave. - Ahvaz- Iran

City

Ahvaz

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Ahvaz Jundishapur 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**

Ahvaz Jundishapur University of Medical Sciences

Full name of responsible person

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Position

MSc/ PhD student of Nutrition

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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