Clinical Trial Protocol
Iranian Registry of Clinical Trials

29 Nov 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

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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 α1 Antitripsin, history of jejunoileal bypass surgery orgastroplasty, experience to perform the total parenteral nutrition at 6 months before, consomption 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
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Ghaem Medical Clinic, Taleghani Ave, Ahvaz, Iran
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Sponsors / Funding sources

1

Sponsor
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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

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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