

Clinical Trial Protocol

Iranian Registry of Clinical Trials

07 Aug 2026

Effect of Calcitriol supplementation on the severity of fatty liver, inflammatory and metabolic biomarkers in patients with non-alcoholic fatty liver with different genotypes of vitamin D receptor

Protocol summary

Study aim

Evaluation of the effects of calcitriol administration on clinical and laboratory parameters in Non-Alcoholic Fatty Liver patients with different genotypes of vitamin D receptor FOK-I polymorphisms

Design

Two arm parallel group double-blind randomised trial with concealed randomization

Settings and conduct

Patients with non-alcoholic fatty liver disease (NAFLD) are recruited from Ahvaz Golestan hospital according to the inclusion/exclusion criteria and receiving the intervention or placebo for 16 weeks following random concealed allocation to the two groups. Participants, healthcare providers (Physicians and nurses) who care for participants during the trial, data collectors, outcome assessors, statistical analyzers and manuscript writers who are involved in our study are blinded.

Participants/Inclusion and exclusion criteria

Inclusion criteria: age between 18- 60 years; the presence of NAFLD diagnosed by Fibroscan elastography; increased alanine transaminase (> 40 U/L); BMI below 35. Exclusion criteria: Alcohol consumption greater than 20 g per day; pregnancy; lactation; viral or autoimmune hepatitis; hereditary hemochromatosis; Wilson's disease; $\alpha 1$ -antitripsin deficiency; malabsorption syndromes; consumption of hepatotoxic drugs; high doses of synthetic estrogens; a history of hypothyroidism and Cushing's syndrome; Serum calcium greater than 10.6 mg/dl; a history of kidney stones; renal failure; intake of vitamin D, vitamin E and calcium supplements during last 3 months.

Intervention groups

Patients with non-alcoholic fatty liver disease (NAFLD) receiving calcitriol or placebo following random allocation

Main outcome variables

Serum levels of liver enzymes; levels of hepatic steatosis

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT2017053034222N1**

Registration date: **2017-06-28, 1396/04/07**

Registration timing: **prospective**

Last update: **2018-03-11, 1396/12/20**

Update count: **1**

Registration date

2017-06-28, 1396/04/07

Registrant information

Name

Hamid Yaghooti

Name of organization / entity

Ahvaz Jundishapur University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 61 3373 8430

Email address

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Recruitment status

Recruitment complete

Funding source

Ahvaz Jundishapur University of Medical Sciences

Expected recruitment start date

2017-09-23, 1396/07/01

Expected recruitment end date

2018-06-22, 1397/04/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of Calcitriol supplementation on the severity of fatty liver, inflammatory and metabolic biomarkers in patients with non-alcoholic fatty liver with different genotypes of vitamin D receptor

Public title

Calcitriol supplementation in Nonalcoholic Fatty Liver Disease

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Age between 18- 60 years Presence of NAFLD diagnosed by Fibroscan elastography Increased alanine transaminase (> 40 U/L) BMI below 35

Exclusion criteria:

Alcohol consumption greater than 20 g per day pregnancy; lactation viral or autoimmune hepatitis hereditary hemochromatosis Wilson's disease α 1-antitrypsin deficiency malabsorption syndromes consumption of hepatotoxic drugs high doses of synthetic estrogens hypothyroidism and Cushing's syndrome Serum calcium greater than 10.6 mg/dl history of kidney stones; renal failure intake of vitamin D, vitamin E and calcium supplements

Age

From **18 years** old to **60 years** old

Gender

Both

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **160**

Randomization (investigator's opinion)

Randomized

Randomization description

Block randomization with blocks of size 6 and random allocation to the blocks and allocation concealment was carried out using A and B codes

Blinding (investigator's opinion)

Double blinded

Blinding description

Participants, healthcare providers (Physicians and nurses) who care for participants during the trial, data collectors, outcome assessors, statistical analyzers and manuscript writers who are involved in our study are blinded.

Placebo

Used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics committee of Ahvaz Jundishapur University of Medical Sciences

Street address

Golestan Blvd., Ahvaz, Iran

City

Ahvaz

Province

Khuzestan

Postal code

61357-15794

Approval date

2017-05-23, 1396/03/02

Ethics committee reference number

IR.AJUMS.REC.1396.161

Health conditions studied**1****Description of health condition studied**

Non-Alcoholic Fatty Liver disease (NAFLD)

ICD-10 code

K76.0

ICD-10 code description

Fatty (change of) liver, not elsewhere classified

Primary outcomes**1****Description**

Liver enzymes

Timepoint

Before and after 16 weeks calcitriol treatment

Method of measurement

Activity assay of enzymes in serum

Secondary outcomes**1****Description**

Hepatic Steatosis

Timepoint

Before and after 16 weeks of calcitriol treatment

Method of measurement

Fibroscan elastography and enzymatic assay of glyceamic and lipid parameters in serum

2**Description**

High sensitive C-reactive protein (hs-CRP)

Timepoint

Before and after 16 weeks of calcitriol treatment

Method of measurement

Enzyme-linked immunosorbent assay

3**Description**

Total adiponectin

Timepoint

Before and after 16 weeks of calcitriol treatment

Method of measurement

Enzyme-linked immunosorbent assay

4**Description**

Serum leptin

Timepoint

Before and after 16 weeks of calcitriol treatment

Method of measurement

Enzyme-linked immunosorbent assay

5**Description**

Glycemic profile

Timepoint

Before and after 16 weeks of calcitriol treatment

Method of measurement

By measuring fasting serum glucose and insulin

6**Description**

Lipid profile

Timepoint

Before and after 16 weeks of calcitriol treatment

Method of measurement

By enzymatic measurement of fasting serum triglyceride, cholesterol, HDL and LDL

Intervention groups**1****Description**

0.25 µg/day calcitriol for 16 weeks

Category

Treatment - Drugs

2**Description**

Calcitriol placebo

Category

Placebo

Recruitment centers**1****Recruitment center**

Name of recruitment center
Golestan hospital

Full name of responsible person

Saied Seyedian

Street address

Golestan Blvd., Ahvaz, Iran

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Email

hmdyaghooti@gmail.com

Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Ahvaz Jundishapur University of Medical Sciences

Full name of responsible person

Mohammad Badavi

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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

Ahvaz Jundishapur University of Medical Sciences

Proportion provided by this source

100

Public or private sector

Public

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin**Type of organization providing the funding**

Academic

Person responsible for general inquiries**Contact****Name of organization / entity**

Ahvaz University of Medical Sciences

Full name of responsible person

Narges Mohammadtaghvaie

Position

Assistant professor

Latest degree

Ph.D.

Other areas of specialty/work

Biochemistry

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Web page address**Person responsible for scientific inquiries****Contact****Name of organization / entity**

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Full name of responsible person

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Position

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Other areas of specialty/work

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Web page address**Person responsible for updating data****Contact****Name of organization / entity**

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Web page address**Sharing plan****Deidentified Individual Participant Data Set (IPD)**

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Not applicable

Data Dictionary

Not applicable

Title and more details about the data/document

SPSS files of results

When the data will become available and for how long

6 months after publication of results

To whom data/document is available

For academic staff

Under which criteria data/document could be used

Further analysis only with permission

From where data/document is obtainable

Dr. Hamid Yaghooti who is in charge of scientific inquiries should be contacted via email.

What processes are involved for a request to access data/document

Applications will be replied within 2 weeks following the required assessments.

Comments