Clinical Trial Protocol
Iranian Registry of Clinical Trials

01 Nov 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; α1-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)

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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 α1-antitripsin 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
Khouzestan

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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61357-33118
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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
Street address
Golestan Blvd., Ahvaz, Iran
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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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Person responsible for updating data

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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