Clinical Trial Protocol
Iranian Registry of Clinical Trials

02 Nov 2026

Vitamin D supplementation for the treatment of non alcoholic fatty liver disease: a randomized double blind placebo controlled trial

Protocol summary

Summary

Objectives: This study aimed to investigate the effect of vitamin D treatment in in patients non -alcoholic fatty liver disease (NAFLD). Design:In a single center randomized double-blind placebo controlled phase 1 trial; 91 participants aged between 20 and 75 years with hepatic steatosis diagnosed by ultrasound (US) are treated with vitamin D capsule (group1), Calcitriol (group 2) and placebo (group 3). Setting and conduct: Patients are randomized to receive weekly 50000 vitamin D capsule (group1), daily 0.25 mg Calcitriol (group 2) and placebo (group 3) for 12 weeks Participants including major inclusion criteria: men and women aged between 20 and 75 years with presence of hepatic steatosis diagnosed by ultrasound (US). patients with chronic liver diseases were excluded Intervention: 50000 vitamin D capsule (group1), daily 0.25 mg Calcitriol (group 2) and placebo (group 3) for 12 weeks Main outcomes: The primary outcome was changes in serum ALT, AST, GGT from baseline to 12 weeks. Secondary outcomes were improvement of metabolic component of patients including fasting plasma glucose, LDL, HDL, triglyceride and total cholesterol.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201612077732N2**
Registration date: **2017-02-26, 1395/12/08**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2017-02-26, 1395/12/08

Registrant information

Name

Ahad Eshraghian

Name of organization / entity

Shiraz University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 71 1612 5600

Email address

eshragha@sums.ac.ir

Recruitment status

Recruitment complete

Funding source

Shiraz University of Medical Sciences

Expected recruitment start date

2014-08-01, 1393/05/10

Expected recruitment end date

2014-11-01, 1393/08/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Vitamin D supplementation for the treatment of non alcoholic fatty liver disease: a randomized double blind placebo controlled trial

Public title

Vitamin D supplementation for the treatment of non alcoholic fatty liver disease: a randomized double blind placebo controlled trial

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: men and women aged between 20 and 75 years with presence of hepatic steatosis diagnosed by ultrasound (US) Exclusion criteria: Patients with liver

cirrhosis; patients with hepatitis B or hepatitis C; patients with alcohol consumption (> 10 gr/ day); patients with autoimmune hepatitis; Wilson’s disease and hemochromatosis; known cancer; nephrolithiasis; nephrocalcinosis; chronic renal failure; hypercalcemia; hypercalciurea; pregnancy; lactation; patients receiving estrogen; tamoxifen; methotrexate; amiodarone; tetracycline and those receiving vitamin D and calcium supplementations in previous 6 months.

Age
From **20 years** old to **75 years** old

Gender
Both

Phase
1

Groups that have been masked
No information

Sample size
Target sample size: **106**

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
Ethics committee of Shiraz university of medical sciences

Street address
zand boulevard

City
SHIRAZ

Postal code

Approval date
2014-02-02, 1392/11/13

Ethics committee reference number
CT-P-9205587

Health conditions studied

1

Description of health condition studied
NON ALCOHOLIC FATTY LIVER DISEASE

ICD-10 code
K76.0

ICD-10 code description

Primary outcomes

1

Description
liver enzymes

Timepoint
begining of the study-3 months after

Method of measurement
biochemicl kit

Secondary outcomes

1

Description
lipid profile and plasma glucose

Timepoint
begining of the study- 3 months later

Method of measurement
Biochemical kit

Intervention groups

1

Description
Intervention group 1:50000 U vitamin D3 (cholecalciferol) pearl (Zahravi Pharmacutical Co) per week for 3 months

Category
Treatment - Drugs

2

Description
Intervention group 2 : Intervention group 2: 0.25 mg calcitriol (1,25 dihydroxycholecalciferol) pearl (Zahravi Pharmacutical Co) per day for 3 months.

Category
Treatment - Drugs

3

Description
Control group: Placebo capsule (Zahravi Pharmacutical Co) /one per week for 3 months

Category
Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
Endocrinology and Metabolism Research Center, Shiraz University of Medical Sciences

Full name of responsible person

Dr. Mohammad Hossein Dabbaghmanesh

Street address

City

Shiraz

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice Chancellor for Research, Shiraz University of Medical Sciences

Full name of responsible person

Basir Hashemi

Street address

5th floor- Research Tower-Namazi hospital-Shiraz-Iran

City

Shiraz

Grant name

-

Grant code / Reference number

-

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

Yes

Title of funding source

Vice Chancellor for Research, Shiraz 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

Eendocrinology and metabolism research center

Full name of responsible person

mohammad hossein dabaghmanesh

Position

Professor

Other areas of specialty/work

Street address

5th floor, Research tower, Namazi hospital, Shiraz, Iran

City

Shiraz

Postal code

Phone

+98 71 3628 1569

Fax

Email

dabbaghmanesh@gmail.com

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity

Endocrinology and Metabolism Research center

Full name of responsible person

Mohamamd hossein Dabbaghmanesh

Position

Professor

Other areas of specialty/work

Street address

5th floor, Research tower, Namazi Hospital, Shiraz

City

Shiraz

Postal code

Phone

+98 71 3628 1569

Fax

Email

dabbaghmanesh@gmail.com

Web page address

Person responsible for updating data

Contact

Name of organization / entity

Shiraz University of Medical Sciences

Full name of responsible person

Ahad Eshraghian

Position

Gastroenterologist and hepatologist

Other areas of specialty/work

Street address

Gastroenterology and hepatology Research Center, Research Tower, Namazi Hospital, Zand Boulevard, Shiraz, Iran

City

Shiraz

Postal code

Phone

+98 36281442

Fax

Email

Eshraghiana@yahoo.com

Web page address

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