Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

The effect of vitamin D supplementation, vitamin D + calcium on fat storage in liver, serum lipoproteins and insulin sensitivity in patients with non-alcoholic fatty liver disease compared with controls.

Protocol summary

Summary

The aim of this study is evaluate the effect of vitamin D supplementation, vitamin D + calcium on fat storage in liver, serum lipoproteins and insulin sensitivity in patients with non-alcoholic fatty liver disease. In this clinical trial, participants (n=120) are 18-65 years old cases who referred to clinics of Iran University of Medical Sciences. Intervention period is 12 weeks. Two packages contain vitamin D (1,000 international units of vitamin D) and placebo (calcium) or vitamin D + calcium (500 mg calcium) or placebo (vitamin D) and placebo (calcium) in the form of a double-blind (Researchers and patients are unaware type of intervention) to the participants in this study given. Randomization is done by draw. Participants will alternately assigned to the intervention or the placebo group. In this study, hepatic steatosis of patients will be measured by Ultrasound before and after intervention.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201408312709N29**
Registration date: **2014-10-11, 1393/07/19**
Registration timing: **prospective**

Last update:
Update count: **0**

Registration date

2014-10-11, 1393/07/19

Registrant information

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Farzad Shidfar
Name of organization / entity
Iran University of Medical Sciences
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Recruitment status

Recruitment complete

Funding source
Vice chancellor for research, iran university of medical sciences

Expected recruitment start date

2014-11-22, 1393/09/01

Expected recruitment end date

2015-03-21, 1394/01/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of vitamin D supplementation, vitamin D + calcium on fat storage in liver, serum lipoproteins and insulin sensitivity in patients with non-alcoholic fatty liver disease compared with controls.

Public title

Effect of vitamin D, vitamin D + calcium supplementation on nonalcoholic fatty liver disease

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Willingness to participate in this clinical trial, do not consume alcohol, not smoking, age 18 to 65 Years, BMI less than 35 (kilograms by the square of height), not taking certain medications (hepatotoxic

drugs such as phenytoin, amiodarone, levothyroxine), not having these diseases (diabetes, heart, liver, kidney, lung), Not having inherited disorders affecting the liver (iron and copper storage disease, etc), not professional athlete, avoiding the use of nutritional supplements in the past 3 months. Exclusion criteria: Unwillingness to cooperate, taking nutritional supplements, pregnancy or lactation, smoking, alcohol consumption, intake of less than 70% of prescribed pills.

Age
From **18 years** old to **65 years** old

Gender
Both

Phase
3

Groups that have been masked
No information

Sample size
Target sample size: **80**

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 Iran University of Medical Sciences

Street address
Faculty of Health, Iran University of Medical Sciences, near milad Hospital, Shahid Hemmat Highway,Tehran, Iran

City
Tehran

Postal code
1449614535

Approval date
2014-09-22, 1393/06/31

Ethics committee reference number
24972

Health conditions studied

1

Description of health condition studied
Nonalcoholic fatty liver disease

ICD-10 code
K76.0

ICD-10 code description
Fatty (change of) liver, not elsewhere classified

Primary outcomes

1

Description
CH

Timepoint
before the experiment.12 weeks after intervention

Method of measurement
END POINT enzymatic method

2

Description
Liver Fat

Timepoint
before the experiment.12 weeks after intervention

Method of measurement
Measured by ultrasound (normal - mild - moderate - severe)

3

Description
Hip circumference

Timepoint
before the experiment.12 weeks after intervention

Method of measurement
By measuring tape

4

Description
Percent body fat

Timepoint
before the experiment.12 weeks after intervention

Method of measurement
BIA

5

Description
HDL

Timepoint
before the experiment.12 weeks after intervention

Method of measurement
DIRECT enzymatic method

6

Description
LDL

Timepoint
before the experiment.12 weeks after intervention

Method of measurement
Using the Fried Wald Equation

7

Description
TG
Timepoint
before the experiment.12 weeks after intervention
Method of measurement
END POINT enzymatic method

8

Description
FBS
Timepoint
before the experiment.12 weeks after intervention
Method of measurement
Glucose oxidase enzymatic colorimetric method

9

Description
Fasting insulin
Timepoint
before the experiment.12 weeks after intervention
Method of measurement
By ELISA (IRMA)

10

Description
Weight
Timepoint
before the experiment.12 weeks after intervention
Method of measurement
Scales

11

Description
BMI
Timepoint
before the experiment.12 weeks after intervention
Method of measurement
Measured height and weight

12

Description
Waist
Timepoint
before the experiment.12 weeks after intervention
Method of measurement
tape

Secondary outcomes

1

Description
Vitamin D supplement
Timepoint
before the experiment.12 weeks after intervention
Method of measurement
Questionnaire

2

Description
Placebo
Timepoint
before the experiment.12 weeks after intervention
Method of measurement
Questionnaire

3

Description
Age
Timepoint
before the experiment
Method of measurement
Questionnaire

4

Description
Height
Timepoint
before the experiment
Method of measurement
Tape

5

Description
Energy intake
Timepoint
before the experiment, 6 weeks after the intervention, 12 weeks after the intervention.
Method of measurement
24-hour recall questionnaire.

6

Description
Protein intake
Timepoint
before the experiment, 6 weeks after the intervention, 12 weeks after the intervention.
Method of measurement
24-hour recall questionnaire.

7

Description
Carbohydrate intake
Timepoint
before the experiment, 6 weeks after the intervention, 12 weeks after the intervention.
Method of measurement
24-hour recall questionnaire.

8

Description
Fat intake
Timepoint

before the experiment, 6 weeks after the intervention, 12 weeks after the intervention.

Method of measurement

24-hour recall questionnaire.

9

Description

Cholesterol intake

Timepoint

before the experiment, 6 weeks after the intervention, 12 weeks after the intervention.

Method of measurement

24-hour recall questionnaire.

10

Description

Vitamin E intake

Timepoint

before the experiment, 6 weeks after the intervention, 12 weeks after the intervention.

Method of measurement

24-hour recall questionnaire.

11

Description

Vitamin C intake

Timepoint

before the experiment, 6 weeks after the intervention, 12 weeks after the intervention.

Method of measurement

24-hour recall questionnaire.

12

Description

Vitamin A intake

Timepoint

before the experiment, 6 weeks after the intervention, 12 weeks after the intervention.

Method of measurement

24-hour recall questionnaire.

13

Description

Omega3 intake

Timepoint

before the experiment, 6 weeks after the intervention, 12 weeks after the intervention.

Method of measurement

24-hour recall questionnaire.

14

Description

Calcium intake

Timepoint

before the experiment, 6 weeks after the intervention, 12 weeks after the intervention.

Method of measurement

24-hour recall questionnaire.

15

Description

Vitamin D intake

Timepoint

before the experiment, 6 weeks after the intervention, 12 weeks after the intervention.

Method of measurement

24-hour recall questionnaire.

16

Description

Physical Activity

Timepoint

before the experiment, 6 weeks after the intervention, 12 weeks after the intervention.

Method of measurement

Questionnaire Physical Activity last 7 days

Intervention groups

1

Description

Placebo: two tablets contain lactose, produced in the company of jalinus, once daily, for 12 weeks.

Category

Placebo

2

Description

Intervention: Vitamin D tablets. Contains 1000 international units of vitamin D, produced in the company of jalinus, once daily, for 12 weeks.

Category

Treatment - Drugs

3

Description

Intervention: One tablet contains 1000 international units of vitamin D + one tablet containing 500 mg of calcium, produced in the company of jalinus, once daily, for 12 weeks

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Rasoul Akram Hospital, Iran University of Medical Sciences

Full name of responsible person

Dr.Shahram agah

Street address

City
Tehran

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice chancellor for research, iran university of medical sciences
Full name of responsible person
Seyed Ali Javad Moosavi
Street address
7th Floor, , Department of Internal Medicine, Hazrat-E-Rasoul Hospital, Iran University of Medical Sciences, Niayesh St., Sattarkahn Ave, Tehran, Iran.
City
Tehran
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, iran 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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Web page address

Person responsible for updating data

Contact

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