

Clinical Trial Protocol

Iranian Registry of Clinical Trials

20 Jun 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

Name

Farzad Shidfar

Name of organization / entity

Iran University of Medical Sciences

Country

Iran (Islamic Republic of)

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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

Contact

Name of organization / entity

Iran University of Medical Sciences

Full name of responsible person

Hamid Lorvand Amiri

Position

Master student

Other areas of specialty/work

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Email

shidfar.f@iums.ac.ir

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