

Clinical Trial Protocol

Iranian Registry of Clinical Trials

20 Jun 2026

The effect of a single dose of vitamin D3 injection on serum 25 hydroxy vitamin D and adiponectin and liver function in women with non-alcoholic fatty liver disease

Protocol summary

Summary

This randomized controlled clinical trial will be performed on 72 patients with NAFLD confirmed by sonographic image, and vitamin D deficiency at baseline, demographic and physical activity questionnaires, and 24-hour dietary recall will be completed for each of the participants and anthropometric indices will be measured. Blood samples will be taken after 12 to 14 hours of fasting for measuring the level of liver enzymes and serum adiponectin and 25-hydroxyvitamin D. Patients will be randomly divided into 2 intervention and control groups. Both of them will receive 1 capsule of vitamin E (400 IU) daily for one month and in the intervention group, patients will be received vitamin D at a dose of 600,000 IU. The anthropometric and biochemical measurements and Sonography of the liver will be repeated at the end of study.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201503163320N10**
Registration date: **2015-07-02, 1394/04/11**
Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2015-07-02, 1394/04/11

Registrant information

Name

Mehrangiz Ebrahimi mamagani

Name of organization / entity

Health & Nutrition faculty of Tabriz university of medical sciences

Country

Iran (Islamic Republic of)

Phone

+98 41 1335 1113

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Recruitment status

Recruitment complete

Funding source

Research deputy of Tabriz University of Medical Sciences

Expected recruitment start date

2015-04-05, 1394/01/16

Expected recruitment end date

2015-09-07, 1394/06/16

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of a single dose of vitamin D3 injection on serum 25 hydroxy vitamin D and adiponectin and liver function in women with non-alcoholic fatty liver disease

Public title

vitamin D and non-alcoholic fatty liver disease

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: willingness to participate in the study, 18-50 years old, liver steatosis on sonographic image, vitamin D deficiency (25(OH)D levels less than 30ng/ml), BMI \geq 25 Exclusion criteria: Alcohol consumption (more than 20g/day), menopause, gestation or lactation, BMI > 40, diabetes and insulin resistance, any other liver disease (viral disease, Wilson, Hemochromatosis,

glycogen storage disorders and etc) or using drugs for the treatment of fatty liver(such as omega-3 and herbal supplements), Thyroid and parathyroid disorders, bone problems, Cushing's syndrome, fat malabsorption, cholecystectomy and any other disease that affect the liver, renal disease(renal failure and nephrolithiasis), using vitamin D, calcium and vitamin E supplements in the past 6 months, taking any drugs causing fatty liver or hepatotoxic drugs(calcium channel blocker,methotrexate,tamoxifen, valproate, diltiazem, amiodarone, isoniazid, corticosteroids and high-dose of estrogen and progesterin, and the use of contraceptives), taking drugs affecting insulin resistance and liver function(Such as metformin, pioglitazone, lovastatin and etc.), get weight loss diet in the past 6 months, using total parenteral nutrition in the past 6 months.

Age

From **18 years** old to **50 years** old

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **72**

Randomization (investigator's opinion)

Randomized

Randomization description**Blinding (investigator's opinion)**

Not blinded

Blinding description**Placebo**

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

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

Ethics Committee of Tabriz University of Medical Sciences

Street address

Tabriz University of Medical Sciences, Golgasht Street, Tabriz

City

Tabriz

Postal code

5166616471

Approval date

2015-05-04, 1394/02/14

Ethics committee reference number

TBZMED.REC.1394.63

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

Non-alcoholic fatty liver disease

ICD-10 code

K76.0

ICD-10 code description

Fatty (change of) liver, not elsewhere classified

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

serum 25(OH)D

Timepoint

Beginning and end of the intervention

Method of measurement

ELIZA

2**Description**

serum Adiponectin

Timepoint

Beginning and end of the intervention

Method of measurement

ELIZA

3**Description**

Liver Enzyme (ALT,AST,ALP)

Timepoint

Beginning and end of the intervention

Method of measurement

IFCC

4**Description**

Liver steatosis

Timepoint

Beginning and end of the intervention

Method of measurement

Liver Sonography

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

anthropometry

Timepoint

Beginning and end of intervention

Method of measurement

Scale and meter and bioelectrical impedance analyzer

2

Description

Energy and nutrient intake

Timepoint

Beginning and end of the intervention

Method of measurement

24- hour dietary recall

3

Description

Physical activity

Timepoint

Beginning and end of intervention

Method of measurement

Physical activity Questionnaire

4

Description

sun exposure

Timepoint

Beginning and end of intervention

Method of measurement

Questionnaire

Intervention groups

1

Description

control group: Vitamin E400, 1 capsule/day for one month

Category

Treatment - Drugs

2

Description

Intervention Group: injection of vitamin D at the dose of 600000 IU at the beginning of study and Vitamin E400, 1 capsule/day for one month

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Sheykholarais clinic

Full name of responsible person

Dr. Mehrangiz Ebrahimimamagani

Street address

Azadi street

City

Tabriz

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice Chancellor for research of Tabriz University of Medical Sciences

Full name of responsible person

Dr. Mehrangiz Ebrahimimamagani

Street address

Nutrition Faculty, Tabriz University of Medical Sciences, Attar Neyshabori Street, Golgasht Street

City

Tabriz

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 of Tabriz 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

Nutrition Faculty, Tabriz University of Medical Sciences

Full name of responsible person

Dr. Mehrangiz Ebrahimimamagani

Position

Nutrition, PhD

Other areas of specialty/work

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Tabriz University of Medical Sciences, Nutrition faculty

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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