Clinical Trial Protocol
Iranian Registry of Clinical Trials

03 Nov 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)

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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≥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 progestin, 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
Begining 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
Begining and end of intervention
Method of measurement
Physical activity Questionnaire

4

Description
sun exposure
Timepoint
Begining 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
Sheykholrais 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
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Person responsible for scientific inquiries

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Person responsible for updating data

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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