Clinical Trial Protocol
Iranian Registry of Clinical Trials

03 Nov 2026

The effect of vitamin D supplementation on serum concentrations of fibrogenic factors, vitamin D receptor and liver-related micro-RNAs in non-alcoholic fatty liver patients

Protocol summary

Summary

(1) Objectives: In this study NAFLD patients will be assessed in order to determine the effects effect of vitamin D supplementation on serum concentrations of fibrogenic factors, vitamin D receptor and liver-related micro-RNAs. (2) Design: This study will be conducted as a randomized controlled trial. (3) Setting and conduct: Subjects were randomly divided into two groups including 23 subjects (taking vitamin D supplement) and control (placebo). For each patient anthropometric measurements (height, weight and waist circumference) and general characteristics will be assessed at the baseline and end of the study will be filled. 24-h food record questionnaire in order to assessment of food intake and physical activity questionnaire will be complete every two week during the trial. 10 cc fasting blood samples from each patient will be taken at the beginning and end of the intervention. (4) Participants including major eligibility criteria: Inclusion criteria consists of: age between 20 and 60 years old; non-alcoholic fatty liver disease diagnosed by a radiologist and hepatologist using ultrasonography into one of three categories (grade 2 or 3); vitamin D deficiency or insufficiency and Exclusion criteria are: alcohol consumption, history of viral hepatitis; acute or chronic liver failure; malignancy; habitual abuse of nonsteroidal anti-inflammatory drugs; antibiotics; Corticosteroids; ... (5) Intervention: Intervention groups will receive daily 1 vitamin D tablets containing 4000 IU vitamin D with meal and control group use the same placebo tablets daily for 12 weeks. (6) Main outcome measures (variables): Serum collagen type 4, laminin, hyaluronic acid, vitamin D receptor, MiR-122, MiR-34a and MiR-21 in both groups before and after the intervention will be measured.

General information

Acronym

-

IRCT registration information

IRCT registration number: **IRCT201405251485N13**
Registration date: **2017-03-14, 1395/12/24**
Registration timing: **prospective**

Last update:
Update count: **0**

Registration date

2017-03-14, 1395/12/24

Registrant information

Name

Ahmad Esmaillzadeh

Name of organization / entity

Department of Nutrition, School of Public Health, Isfahan University of Medical Sciences

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Recruitment status

Recruitment complete

Funding source

Vice chancellor for Research, Tehran University of Medical Sciences

Expected recruitment start date

2017-04-21, 1396/02/01

Expected recruitment end date

2017-09-21, 1396/06/30

Actual recruitment start date

empty

Actual recruitment end date
empty
Trial completion date
empty

Scientific title
The effect of vitamin D supplementation on serum concentrations of fibrogenic factors, vitamin D receptor and liver-related micro-RNAs in non-alcoholic fatty liver patients

Public title
The effect of vitamin D supplementation on liver fibrosis in non-alcoholic fatty liver patients
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria consists of: age between 20 and 60 years old, non- alcoholic fatty liver disease diagnosed by a radiologist and hepatologist using ultrasonography into one of three categories (grade 2 or 3); vitamin D deficiency or insufficiency and Exclusion criteria are: alcohol and tobacco consumption; Pregnancy; lactation; history of viral hepatitis, acute or chronic liver failure; cholestasis; liver transplantation; habitual abuse of nonsteroidal anti-inflammatory drugs; antibiotics; anti-secretory drugs cause achlorhydria within 9 months before the study; Corticosteroids; using hormonal drugs such as estrogen; hereditary hemochromatosis and Wilson disease; alpha-1 antitrypsin deficiency; diabetes; history of heart failure; kidney disease and kidney stones; malignancy or neoplasia; consumption of vitamin D or antioxidants supplements and weight loss during past 3 month; weight loss surgery during past year; being pregnant; consumption of antioxidants supplement; weight loss more than 2 kg during the study; alcohol and tobacco during the study.
Age
From **20 years** old to **60 years** old
Gender
Both

Phase
2-3
Groups that have been masked
No information
Sample size
Target sample size: **46**
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 Tehran University of Medical Sciences
Street address
Keshavarz blv., Ghods st.
City
Tehran
Postal code
Approval date
2017-02-08, 1395/11/20
Ethics committee reference number
IR.TUMS.VCR.REC.1395.1683

Health conditions studied

1

Description of health condition studied
Non-alcoholic fatty liver
ICD-10 code
K76.0
ICD-10 code description
Fatty (change of) liver, not elsewhere classified

Primary outcomes

1

Description
hyaluronic acid
Timepoint
Baseline and 12 weeks after intervention
Method of measurement
ELISA assay

2

Description
laminin
Timepoint
Baseline and 12 weeks after intervention
Method of measurement
ELISA assay

3

Description
Collagen type 4
Timepoint
Baseline and 12 weeks after intervention
Method of measurement
ELISA assay

4

Description
Vitamin D receptor
Timepoint
Baseline and 12 weeks after intervention
Method of measurement
ELISA assay

5

Description
MiR-122
Timepoint
Baseline and 12 weeks after intervention
Method of measurement
Real-time PCR

6

Description
MiR-34a
Timepoint
Baseline and 12 weeks after intervention
Method of measurement
Real-time PCR

7

Description
MiR-21
Timepoint
Baseline and 12 weeks after intervention
Method of measurement
Real-time PCR

Secondary outcomes

1

Description
AST
Timepoint
Baseline and 12 weeks after intervention
Method of measurement
ELISA assay

2

Description
PTH
Timepoint
Baseline and 12 weeks after intervention
Method of measurement
ELISA assay

3

Description
nutritional status (calorie and nutrients intake)
Timepoint
Every 2 weeks during the intervention
Method of measurement
Food record questionnaire

4

Description
Anthropometric index(weight, height,WHR and Body Mass Index)
Timepoint
Baseline and 12 weeks after intervention
Method of measurement
Analogue scale for weight, height, WHR and weight(Kg)/Square Height for body mass index

5

Description
Physical activity
Timepoint
Every 2 weeks during the intervention
Method of measurement
International Physical Activity questionnaire

6

Description
Fasting blood glucose
Timepoint
Baseline and 12 weeks after intervention
Method of measurement
Enzymatic colorimetric

7

Description
Fasting insulin serum
Timepoint
Baseline and 12 weeks after intervention
Method of measurement
ELISA assay

8

Description
Insulin resistance
Timepoint
Baseline and 12 weeks after intervention
Method of measurement
HOMA-IR calculation

9

Description
Insulin sensitivity
Timepoint
Baseline and 12 weeks after intervention
Method of measurement
QUICKI calculation

10

Description
Lipid profiles (TC, TG, LDL-C, HDL-C)
Timepoint
Baseline and 12 weeks after intervention

Method of measurement
Enzymatic methods for TC,TG and HDL-C For LDL-C : Freidwald's formula: LDL-C = TC- HDL-C - (TG/5)

11

Description
ALT
Timepoint
Baseline and 12 weeks after intervention
Method of measurement
ELISA assay

Intervention groups

1

Description
Intervention group will receive daily 1 tablets of vitamin D with meal for 12 weeks. Vitamin D tablets will be purchased from the Pars minoo Company. All the patients will be monitored for consumption of tablets by daily checklists and recall messages.
Category
Treatment - Drugs

2

Description
The control group will receive daily 1 tablets of placebo with meal for 12 weeks. placebo tablets will be purchased from the Pars minoo Company. All the patients will be monitored for consumption of tablets by daily checklists and recall messages.
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Digestive disease research institute, Tehran Shariaty hospital
Full name of responsible person
Soraiya Ebrahimpour-Koujan
Street address
kargar-e-shomali st. jalal aal ahmad st.
City
Tehran

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice chancellor for Research, Tehran University of Medical Sciences
Full name of responsible person
Mis. Khoshtarkib
Street address
Keshavarz blv., Ghods st.
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, Tehran 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
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Dr. Ahmad Esmaillzadeh
Position
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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