# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

20 Jun 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

**Country**

Iran (Islamic Republic of)

**Phone**

+98 31 1792 2791

**Email address**

esmaillzadeh@hlth.mui.ac.ir


**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**
Tehran University of Medical Sciences
**Full name of responsible person**
Dr. Ahmad Esmaillzadeh
**Position**
PhD in Nutritional Sciences, Professor
**Other areas of specialty/work**
**Street address**
Keshavarz Beulvard, Naderi St, Hojjatdoust alley, No 44 , schools of nutritional sciences and dietetics
**City**
Tehran
**Postal code**
-
**Phone**
+98 21 8895 5569
**Fax**
**Email**
a.esmaillzadeh@gmail.com
**Web page address**

## Person responsible for scientific inquiries

**Contact**
**Name of organization / entity**
Tehran University of Medical Sciences
**Full name of responsible person**
Dr. Ahmad Esmaillzadeh
**Position**
PhD in Nutritional Sciences, Professor
**Other areas of specialty/work**
**Street address**

Keshavarz Beulvard, Naderi St, Hojjatdoust alley, No 44 , schools of nutritional sciences and dietetics

**City**
Tehran

**Postal code**
-

**Phone**
+98 21 8895 5569

**Fax**
-

**Email**
a.esmaillzadeh@gmail.com

**Web page address**

## Person responsible for updating data

**Contact**

**Name of organization / entity**
Tehran University of Medical Sciences

**Full name of responsible person**
Soraiya Ebrahimpour-Koujan

**Position**
PhD student in Nutrition Sciences

**Other areas of specialty/work**

**Street address**
Keshavarz Beulvard, Naderi St, Hojjatdoust alley, No 44 , schools of nutritional sciences and dietetics

**City**
Tehran

**Postal code**
-

**Phone**
00

**Fax**

**Email**
nutri.seam1@gmail.com

**Web page address**

## 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*