

Clinical Trial Protocol

Iranian Registry of Clinical Trials

28 Jun 2026

Evaluation of vitamin D administration in non-alcoholic fatty liver disease (NAFLD)

Protocol summary

Summary

Objectives: This study was performed to evaluate the efficacy of Vitamin D in nonalcoholic fatty liver disease (NAFLD) patients. Design: Study sample were patients who had elevated liver enzymes and referred to subspecialized gastrointestinal clinic and diagnosed as NAFLD with conducted assessment. The patients whose level vitamin D less than 30 nanogram enrolled. At first, fibroscan will be performed for all of patients. The intervention group (20 individuals) will receive 50000 International Unit vitamin D in each week for 12 weeks, besides lifestyle modification with daily nutritional program, daily energy regulation on 2000 calorie in females and 2500 calorie in males. The control group will receive only lifestyle modification program. Two groups will be matched with random number table. The patients weight and length will be measured with digital Seca scale. Two groups will be matched about age, gender, body mass index and the severity of fatty liver disease. The patients will be followed up for 6 months: Body Mass Index and the level of aminotransferase will be checked, and fibroscan will be performed and the results will be compared within two groups.

General information

Acronym

-

IRCT registration information

IRCT registration number: **IRCT2015102624725N1**

Registration date: **2016-01-03, 1394/10/13**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2016-01-03, 1394/10/13

Registrant information

Name

Tarang Taghvaei

Name of organization / entity

Mazandaran University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 11 3335 0670

Email address

gi-research-1@mazums.ac.ir

Recruitment status

Recruitment complete

Funding source

Vice chancellor for research Mazandaran University of Medical Sciences

Expected recruitment start date

2014-08-23, 1393/06/01

Expected recruitment end date

2015-12-21, 1394/09/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of vitamin D administration in non-alcoholic fatty liver disease (NAFLD)

Public title

The efficacy of vitamin D administration in non-alcoholic fatty liver disease (NAFLD)

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion Criteria: ALT rising equals or more than 2 times of normal level; probable diagnosis of Nonalcoholic Steatohepatitis and rule out of other hepatic-enzymes

rising causes such as viral and autoimmune hepatitis; age more than 18 years; serum vitamin D level less than 30 nanogram per milliliter Exclusion Criteria: hepatic cirrhosis; pregnancy or breast-feeding; alcohol use ; substance abuse;vitamin D administration in 6 months ago, weight loss more than 5% in 1 year ago; newly-diagnosed diabetes (in the recent 1 year) which needs treatment: antioverweight medication ; hypercalcemia; chronic renal disease; life-threatening cardiopulmonary diseases ; hyperlipidemia which needs medication; medications which affect on hepatic enzymes

Age

No age limit

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: 40

Randomization (investigator's opinion)

Randomized

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

Not blinded

Blinding description**Placebo**

Not used

Assignment

Single

Other design features

Two groups will be matched with random number table.

Secondary Ids

empty

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

Ethics Committee of Mazandaran University of Medical Sciences

Street address

Vice chancellor of research, Unit number 2, Moallem Square, Sari

City

Sari

Postal code**Approval date**

2015-05-13, 1394/02/23

Ethics committee reference number

1144

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

Nonalcoholic fatty liver disease (NAFLD)

ICD-10 code

K76.0

ICD-10 code description

Nonalcoholic fatty liver disease (NAFLD)

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

the level of aminotransferases

Timepoint

3th and 6th month

Method of measurement

biochemical

2**Description**

Fibroscan and BMI

Timepoint

3th and 6th month for BMI and 6th month for fibroscan

Method of measurement

fibroscan and anthropometric measurement(kg/m2)

Secondary outcomes

empty

Intervention groups**1****Description**

Intervention:administration of vitamin D pearl and life style modification

Category

Treatment - Drugs

2**Description**

Control: lifestyle modification

Category

Lifestyle

Recruitment centers**1****Recruitment center****Name of recruitment center**

Imam Hospital

Full name of responsible person

Tarang Taghvaei

Street address

Imam Hospital, Amir Mazandarani Avenue, Sari

City

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice Chancellor for Research Mazandaran University of Medical Sciences

Full name of responsible person

Ahmad Ali Enayati

Street address

Sari, Moallem Square, Unit number 2, Vice chancellor of research

City

Sari

Grant name

معاونت پژوهشی دانشگاه علوم پزشکی مازندران

Grant code / Reference number
Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Vice Chancellor for Research Mazandaran 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

Mazandaran University of Medical Sciences

Full name of responsible person

Tarang Taghvaei

Position

Assistant Professor

Other areas of specialty/work
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Position

Subspecialist in GI disorders

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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