Clinical Trial Protocol
Iranian Registry of Clinical Trials

03 Nov 2026

Evaluation of vitamin D administration in non-alchoholic 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 whoose level vitamin D less than 30 nanogram endrolled. At first, fibroscan will be performed for all of patients. The intervention group (20 individuals) will receive 50000International 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 patiens 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
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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-alchoholic fatty liver disease(NAFLD)

Public title

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

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion Criteria: ALT rising equals or more than 2times 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 mililiter 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

Sari

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
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Position
Assisstant Professor

Other areas of specialty/work

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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