Clinical Trial Protocol
Iranian Registry of Clinical Trials

25 Nov 2026

The comprasion Of Active and Inactive Vit D On Non Alcoholic Fatty Liver(NAFLD)

Protocol summary

Summary

This study tries to compare between the active and non-active forms of Vitamin D in improving non-alcoholic fatty liver disease. 90 patients are selected by a gastroenterologist after their diseases diagnosis and having study entrance inclusion criteria. All patients will sign the satisfaction form. Initially the patients' vitamin D level, fat profile and their liver enzymes of ALT and AST will be measured and registered. The patients will be selected randomly and they are divided into three groups of 30 each through permutation blocks. First group: receiving medication (Rocaltrol) capsules (soft gel) 1mcg/day Second group: receiving medication (vitamin D3) capsules (soft gel) 50000UI/week Third group: control The patients use the drugs for 8 weeks and then the primary experiments will be repeated and recorded. ANOVA will be used to compare the results of liver enzymes and fat profile in three groups and if there is a difference among three groups the post hoc test is used to compare them.

General information

Acronym

Non Alcoholic Fatty Liver(NAFLD)

IRCT registration information

IRCT registration number: **IRCT2015010720595N1**
Registration date: **2015-11-16, 1394/08/25**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2015-11-16, 1394/08/25

Registrant information

Name

Zahra Almoosavi

Name of organization / entity

Shiraz School of Pharmacy

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Iran (Islamic Republic of)

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+98 71 3242 4128

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Recruitment status

Recruitment complete

Funding source

Shiraz University of Medical Sciences, Shiraz School of Pharmacy

Expected recruitment start date

2015-08-02, 1394/05/11

Expected recruitment end date

2015-10-07, 1394/07/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The comprasion Of Active and Inactive Vit D On Non Alcoholic Fatty Liver(NAFLD)

Public title

The comprasion Of Active and Inactive Vit D On Non Alcoholic Fatty Liver(NAFLD)

Purpose

Treatment

Inclusion/Exclusion criteria

The study inclusion criteria: the patients by NAFLD (non-alcoholic fatty liver disease) definition; age>18 years old; patient's cooperation. The study exclusion criteria: any liver disease except for NAFLD; alcohol consumption and any addictive drugs; lactating or pregnant patients; noncooperation or dissatisfaction of the patient; any drug

consumption that may affect NAFLD.

Age
From **18 years** old to **60 years** old

Gender
Both

Phase
2-3

Groups that have been masked
No information

Sample size
Target sample size: **90**

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
Shiraz School of Pharmacy

Street address
Shiraz School of Pharmacy, Karafarin St., Darvaze Qhoran 5 km, Roknabad ,

City
Shiraz

Postal code
7146864685

Approval date
2015-08-02, 1394/05/11

Ethics committee reference number
IR.SUMS.REC.1394088

Health conditions studied

1

Description of health condition studied
Non Alcoholic Fatty Liver

ICD-10 code
K760

ICD-10 code description
Fatty (change of) liver, not elsewhere classified

Primary outcomes

1

Description
Vit D

Timepoint
Before intervention and 2 month after it

Method of measurement
Blood test

2

Description
ALT

Timepoint
Before intervention and 2 month after it

Method of measurement
Blood Test

3

Description
AST

Timepoint
Befor intervention and 2 month after it

Method of measurement
Blood test

4

Description
Lipid profile

Timepoint
Befor intervention and 2 month after it

Method of measurement
Blood test

Secondary outcomes

empty

Intervention groups

1

Description
Group A: received medication (Rocaltrol) capsules (soft gel) 1mcg/day

Category
Treatment - Drugs

2

Description
Group B: received medication (vitD3) capsules (soft gel) 50000IU/week

Category
Treatment - Drugs

3

Description
Group C: control

Category
N/A

Recruitment centers

1

Recruitment center
Name of recruitment center
Motahari & Faqihi clinic
Full name of responsible person
Dr. Ramin Niknam
Street address
City
Shiraz

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Shiraz University of Medical Sciences
Full name of responsible person
Dr. Ali Dehshahri
Street address
Shiraz University of Medical Sciences, 5 km Darvaze Qoran
City
Shiraz
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Shiraz 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
Shiraz School of Pharmacy
Full name of responsible person
Dr. Laleh Mahmoudi
Position
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Other areas of specialty/work
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Person responsible for updating data

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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