

Clinical Trial Protocol

Iranian Registry of Clinical Trials

28 Jun 2026

The comparison 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

Country

Iran (Islamic Republic of)

Phone

+98 71 3242 4128

Email address

moosaviz@sums.ac.ir

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

Public title

The comparison 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

Before intervention and 2 month after it

Method of measurement

Blood test

4

Description

Lipid profile

Timepoint

Before 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

Assistant Professor

Other areas of specialty/work

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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