

Clinical Trial Protocol

Iranian Registry of Clinical Trials

19 Jul 2026

To Survey effect of Selimarine, Vit E, and Metformine in nonalcoholic fatty liver patients

Protocol summary

Summary

The main aim of this study is to investigate the effect of Silymarin, Metformine, and Vit E on liver enzymes levels in fatty liver patients. 135 patients with fatty liver are recruited and randomly assigned into three equal number groups to receive Silymarin receive 70 mg daily, Metformine 500mg twice daily, or vitamin E 400 mg daily for two months. Liver enzymes are measured in all patients and changes are compared between groups.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT138902253933N1**
Registration date: **2010-04-21, 1389/02/01**
Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2010-04-21, 1389/02/01

Registrant information

Name

Nadia Asadi

Name of organization / entity

Kermanshah University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 83 1427 4889

Email address

mtaran@razi.ac.ir

Recruitment status

Recruitment complete

Funding source

Kermanshah University of Medical Sciences

Expected recruitment start date

2010-04-21, 1389/02/01

Expected recruitment end date

2011-07-23, 1390/05/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

To Survey effect of Selimarine, Vit E, and Metformine in nonalcoholic fatty liver patients

Public title

To Survey effect of Selimarine, Vit E, and Metformine in nonalcoholic fatty liver patients

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: presence of fatty liver
Exclusion criteria: alcoholism, another disease such as viral Hepatitis, pregnancy

Age

No age limit

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **135**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Single blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

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

Kermanshah University of Medical Sciences

Street address

Emam Reza Hospital, Baghe abrisham, Kermanshah

City

Kermanshah

Postal code**Approval date**

2009-10-13, 1388/07/21

Ethics committee reference number

29981/420/7

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

Nonalcoholic Fatty liver

ICD-10 code

K71, K72,

ICD-10 code description

Diseases of the digestive system

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

Serum levels of liver enzymes

Timepoint

before intervention, 2 months after intervention

Method of measurement

Counter

Secondary outcomes

empty

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

Metformine (oral tablet, 500mg twice daily for 2 months)

Category

Treatment - Drugs

2**Description**

Silymarin (oral tablet, 70 mg daily for 2 months)

Category

Treatment - Drugs

3**Description**

Vit E (oral tablet, 400 mg daily for 2 months)

Category

Treatment - Drugs

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

Kermanshah University of Medical Sciences

Full name of responsible person**Street address****City**

Kermanshah

Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Kermanshah University of Medical Sciences

Full name of responsible person

Dr Asadi

Street address

Emam reza hospital

City

Kermanshah

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

Yes

Title of funding source

Kermanshah 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**

Kermanshah University of Medical Sciences

Full name of responsible person

Nadia asadi

Position

Internal resident

Other areas of specialty/work

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Person responsible for scientific inquiries

Contact

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Full name of responsible person

Nadia Asadi

Position

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Nadia Asadi

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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