Clinical Trial Protocol
Iranian Registry of Clinical Trials

04 Nov 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 Haspital, 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 haspital
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 Universityof Medical Sciences
Full name of responsible person
Nadia asadi
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Internal resident
Other areas of specialty/work
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Person responsible for updating data

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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