Clinical Trial Protocol
Iranian Registry of Clinical Trials

04 Nov 2026

Effect of silymarin, metformin, and life style in patients with non-alcoholic fatty liver disease in Marvdasht Hospital

Protocol summary

Study aim
The aim of this study is to compare effectiveness of Silymarin and Metformin in improving some biochemical markers in NAFLD

Design
Randomized double-blinded, placebo-controlled trial

Settings and conduct
Outpatient clinic of Shahid Motahari hospital (Marvdasht) during 6 months period.

Participants/Inclusion and exclusion criteria
Patients aged between 18 to 60 years with probable diagnosis of NAFLD in liver sonography with or without increased levels of liver enzymes will be enrolled in the study. Exclusion criteria includes a history of alcohol consumption, diabetes, and chronic liver disease.

Intervention groups
The patients will be randomly allocated into three study groups; group A subjects were treated with only lifestyle modification and placebo. Group B subjects were administered with lifestyle modification and Metformin 500 mg/day. Group C subjects with lifestyle modification and Silymarin 140 mg/day. Treatment courses were considered for three months.

Main outcome variables
The primary outcome is biomarker changes of liver function test at initial and 3 months after intervention. In addition, we will be considered BMI as secondary outcomes.

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20121105011375N5**
Registration date: **2018-05-10, 1397/02/20**
Registration timing: **prospective**
Last update: **2018-05-10, 1397/02/20**
Update count: **0**

Registration date
2018-05-10, 1397/02/20

Registrant information

Name
pouya farhadi

Name of organization / entity
Shiraz University of Medical Sciences

Country
Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2018-05-22, 1397/03/01

Expected recruitment end date
2018-09-21, 1397/06/30

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Effect of silymarin, metformin, and life style in patients with non-alcoholic fatty liver disease in Marvdasht Hospital

Public title
Effect of Silymarin, Metformin, and life style in non-alcoholic fatty liver disease

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Patients with NAFLD confirmed by performing liver sonography Increased levels of liver enzymes AST and ALT

Exclusion criteria:

History of alcohol consumption Diabetes Chronic liver disease Use of drugs such as statin, fibrate

Age

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

Gender

Both

Phase

N/A

Groups that have been masked

- Participant
- Care provider
- Investigator
- Data analyser

Sample size

Target sample size: **90**

Randomization (investigator's opinion)

Randomized

Randomization description

Randomization will be done using a randomization table based on the registration number of the patients. Study pills will be allocated in separate packs blinded and labeled using a four-digit code.

Blinding (investigator's opinion)

Double blinded

Blinding description

Apart from the outcome assessor, patients, care provider, investigator, and members collecting and analyzing data will be blinded to the intervention allocation.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Shiraz University of Medical Sciences

Street address

Building of Shiraz University of Medical Sciences, Zand Ave

City

Shiraz

Province

Fars

Postal code

71348-45794

Approval date

2018-04-16, 1397/01/27

Ethics committee reference number

IR.SUMS.MED.REC.1397.05

Health conditions studied

1

Description of health condition studied

Non-alcoholic fatty liver

ICD-10 code

K75.81

ICD-10 code description

Nonalcoholic steatohepatitis (NASH)

Primary outcomes

1

Description

Liver function test

Timepoint

Before intervention, 3 months after intervention

Method of measurement

ELISA

Secondary outcomes

1

Description

Body Mass Index

Timepoint

Before intervention, 3 months after intervention

Method of measurement

By BMI Formula

Intervention groups

1

Description

Intervention group: lifestyle modification and Metformin 500 mg/day for 3 months

Category

Treatment - Drugs

2

Description

Intervention group: lifestyle modification and Silymarin 140 mg/day for 3 months

Category

Treatment - Drugs

3

Description

Control group: lifestyle modification and placebo for 3 months

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
Motahari Hospital and Clinic

Full name of responsible person
Amir Anushiravani

Street address
Motahari hospital and clinic, Moalem Square

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Marvdasht

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Shiraz University of Medical Sciences

Full name of responsible person
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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
Public

Domestic or foreign origin
Domestic

Category of foreign source of funding
empty

Country of origin

Type of organization providing the funding
Academic

Person responsible for general inquiries

Contact

Name of organization / entity
Shiraz University of Medical Sciences

Full name of responsible person
Maedeh Pourfarmanbar

Position
General physician

Latest degree
Medical doctor

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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available

Study Protocol
Yes - There is a plan to make this available

Statistical Analysis Plan
Yes - There is a plan to make this available

Informed Consent Form
Yes - There is a plan to make this available

Clinical Study Report
Yes - There is a plan to make this available

Analytic Code
Yes - There is a plan to make this available

Data Dictionary
Yes - There is a plan to make this available

Title and more details about the data/document
The patients will be randomly divided into three study groups; group A subjects will be treated with only lifestyle modification and placebo. Group B subjects will be administered with lifestyle modification and Metformin 500 mg/day. Group C subjects will be received lifestyle modification and Silymarin 140 mg/day. The primary outcomes are biomarker changes including AST, ALT, FBS, TG, CHOL, LDL, and HDL at initial and 3 months after intervention. In addition, we will be considered BMI, and waist circumference as secondary outcomes. All data related to the patients will be shared after deidentifing the patients.

When the data will become available and for how long
starting 1 month after publication

To whom data/document is available
This only available for people working in academic institutions

Under which criteria data/document could be used
All statistical analysis are allowed in line with the objectives of the study. Application terms for access to data including: People working in academic institutions who have registered a protocol liked our study. People are committed to data protection.

From where data/document is obtainable
Vahid Mohammad Karimi, Shiraz Nemazee Hospital, Email: mohamadkv@sums.ac.ir

What processes are involved for a request to access data/document
Through automation correspondence or email

Comments