

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 Jun 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)

Phone

+98 71 1625 4206

Email address

farhadip@sums.ac.ir

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

City

Marvdasht

Province

Fars

Postal code

71879-15998

Phone

+98 71 3634 4292

Email

anushirvan@sums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shiraz University of Medical Sciences

Full name of responsible person

Dr. Seyed Baser Hashemi

Street address

Building of Shiraz University of Medical Sciences,
Zand Ave

City

Shiraz

Province

Fars

Postal code

71345-1978

Phone

+98 71 3235 7282

Email

vcrdep@sums.ac.ir

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

Other areas of specialty/work

Internal Medicine

Street address

Shiraz Medical School, Zand Ave.

City

Shiraz

Province

Fars

Postal code

71348-45794

Phone

+98 71 3230 5645

Email

taranehh99@yahoo.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

Shiraz University of Medical Sciences

Full name of responsible person

Vahid Mohammad Karimi

Position

Assistant professor

Latest degree

Specialist

Other areas of specialty/work

Internal Medicine

Street address

Department of Internal Medicine, Nemazee Hospital,
Zand Ave

City

Shiraz

Province

Fars

Postal code

71937-11351

Phone

+98 71 3647 4332

Email

mohamadkv@sums.ac.ir

Person responsible for updating data

Contact

Name of organization / entity

Shiraz University of Medical Sciences

Full name of responsible person

Vahid Mohammad Karimi

Position

Assistant professor

Latest degree

Specialist

Other areas of specialty/work

Internal Medicine

Street address

Department of Internal Medicine, Nemazee Hospital,
Zand Ave

City

Shiraz

Province

Fars

Postal code

71937-11351

Phone

+98 71 3647 4332

Email

mohamadkv@sums.ac.ir

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 deidentifying 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