

Clinical Trial Protocol

Iranian Registry of Clinical Trials

24 Jun 2026

The Combined Effect of Silybum marianum, Cynara scolymus, Curcuma longa and Taraxacum officinale extracts on metabolic parameters, oxidative stress biomarkers and inflammation in patients with Non-alcoholic fatty liver disease

Protocol summary

Study aim

The aim of the present study was to investigate the combined effect of Silybum marianum, Cynara scolymus, Curcuma longa and Taraxacum officinale extracts on metabolic parameters, oxidative stress biomarkers and inflammation in patients with Non-alcoholic fatty liver disease

Design

Random assignment was done by the use of computer-generated random numbers. Population and sample size: In the study 60 patients with Non-alcoholic fatty liver disease among patients of eligible and referred to Velayat hospital affiliated to Qazvin University of Medical Sciences, Qazvin, Iran, will be selected.

Settings and conduct

In the study 60 patients with Non-alcoholic fatty liver disease among patients of eligible and referred to Velayat hospital affiliated to Qazvin University of Medical Sciences, Qazvin, Iran, will be selected.

Participants/Inclusion and exclusion criteria

In this study, patients aged 30 to 70, with Non-alcoholic fatty liver disease will be included. Unwillingness to cooperate, diabetic patients, Smokers, alcoholics and consumers of nerve drugs will be excluded from the study.

Intervention groups

Patients will be assigned to receive either combined extract (intervention group: n=30) or placebo (control group: n=30).

Main outcome variables

Metabolic parameters, oxidative stress biomarkers and inflammation will be measured in patients with Non-alcoholic fatty liver disease before and after of the intervention.

General information

Reason for update

Acronym

Fatty Liver

IRCT registration information

IRCT registration number: **IRCT20170430033730N2**
Registration date: **2018-07-02, 1397/04/11**
Registration timing: **registered_while_recruiting**

Last update: **2018-07-02, 1397/04/11**

Update count: **0**

Registration date

2018-07-02, 1397/04/11

Registrant information

Name

Seyyed Mehdi Mirhashemi

Name of organization / entity

Qazvin University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 28 3333 6001

Email address

sm.mirhashemi@qums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-06-20, 1397/03/30

Expected recruitment end date

2018-07-19, 1397/04/28

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date
empty

Scientific title
The Combined Effect of Silybum marianum, Cynara scolymus, Curcuma longa and Taraxacum officinale extracts on metabolic parameters, oxidative stress biomarkers and inflammation in patients with Non-alcoholic fatty liver disease

Public title
The Combined Effect of Silybum marianum, Cynara scolymus, Curcuma longa and Taraxacum officinale extracts on fatty liver

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
Patients with Non-alcoholic fatty liver disease
Exclusion criteria:
patients who do not want to cooperate People who smoke People who drink alcohol Patients with gastrointestinal disorders Patients who take nerve medications Diabetic Patients

Age
From **30 years** old to **70 years** old

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **60**

Randomization (investigator's opinion)
Randomized

Randomization description
Simple randomization

Blinding (investigator's opinion)
Double blinded

Blinding description
A placebo was used to blind. Researchers and Patients will be blinded by the professional analyst until final analysis.

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Qazvin University of Medical

Sciences
Street address
Shahid Bahonar Boulevard
City
Qazvin
Province
Qazvin
Postal code
34197-59811
Approval date
2018-03-06, 1396/12/15
Ethics committee reference number
IR.QUMS.REC.1396.491

Health conditions studied

1

Description of health condition studied

Non-alcoholic fatty liver

ICD-10 code

K76.0

ICD-10 code description

Fatty (change of) liver, not elsewhere classified

Primary outcomes

1

Description

FBS

Timepoint

At the beginning of the study and 12 weeks after the intervention

Method of measurement

Spectrophotometry

2

Description

Insulin

Timepoint

At the beginning of the study and 12 weeks after the intervention

Method of measurement

ELISA

Secondary outcomes

1

Description

TG

Timepoint

At the beginning of the study and 12 weeks after the intervention

Method of measurement

Spectrophotometry

2

Description

Cholesterol

Timepoint

At the beginning of the study and 12 weeks after the intervention

Method of measurement

Spectrophotometry

3

Description

HDL

Timepoint

At the beginning of the study and 12 weeks after the intervention

Method of measurement

Spectrophotometry

4

Description

LDL

Timepoint

At the beginning of the study and 12 weeks after the intervention

Method of measurement

Spectrophotometry

5

Description

AST

Timepoint

At the beginning of the study and 12 weeks after the intervention

Method of measurement

Spectrophotometry

6

Description

ALT

Timepoint

At the beginning of the study and 12 weeks after the intervention

Method of measurement

Spectrophotometry

7

Description

Glutathion

Timepoint

At the beginning of the study and 12 weeks after the intervention

Method of measurement

Spectrophotometry

8

Description

MDA

Timepoint

At the beginning of the study and 12 weeks after the

intervention

Method of measurement

Spectrophotometry

9

Description

IL-1

Timepoint

At the beginning of the study and 12 weeks after the intervention

Method of measurement

ELISA

10

Description

TNF- α

Timepoint

At the beginning of the study and 12 weeks after the intervention

Method of measurement

ELISA

Intervention groups

1

Description

Intervention group: Two capsules of 275 mg of combined extract were taken twice daily for twelve weeks

Category

Treatment - Drugs

2

Description

Control group: Two capsules of 275 mg of placebo were taken twice a day for 12 weeks

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Velayat Hospital

Full name of responsible person

Seyyed Mehdi Mirhashemi

Street address

Shahid Bahonar Blovard

City

Qazvin

Province

Qazvin

Postal code

34197-59811

Phone

+98 28 3333 6001

Email

mirhashemism@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Qazvin University of Medical Sciences

Full name of responsible person

Amir Peimani

Street address

Shahid Beheshti Blvd - Valiasr Square

City

Qazvin

Province

Qazvin

Postal code

34156-13911

Phone

+98 28 3333 7006

Email

a.peymani@gmail.com

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Qazvin 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

Qazvin University of Medical Sciences

Full name of responsible person

Seyyed Mehdi Mirhashemi

Position

Associate professor

Latest degree

Ph.D.

Other areas of specialty/work

Biochemistry

Street address

Shahid Bahonar Blovard

City

Qazvin

Province

Qazvin

Postal code

34197-59811

Phone

+98 28 3333 6001

Email

mirhashemism@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

Qazvin University of Medical Sciences

Full name of responsible person

Seyyed Mehdi Mirhashemi

Position

Associate professor

Latest degree

Ph.D.

Other areas of specialty/work

Biochemistry

Street address

Shahid Bahonar Blovard

City

Qazvin

Province

Qazvin

Postal code

34197-59811

Phone

+98 28 3333 6001

Email

mirhashemism@gmail.com

Person responsible for updating data

Contact

Name of organization / entity

Qazvin University of Medical Sciences

Full name of responsible person

Seyyed Mehdi Mirhashemi

Position

Associate professor

Latest degree

Ph.D.

Other areas of specialty/work

Biochemistry

Street address

Shahid Bahonar Blovard

City

Qazvin

Province

Qazvin

Postal code

34197-59811

Phone

+98 28 3333 6001

Email

mirhashemism@gmail.com

Sharing plan

Deidentified Individual Participant Data Set (IPD)

No - There is not a plan to make this available
Justification/reason for indecision/not sharing IPD
There is no further information
Study Protocol
No - There is not a plan to make this available
Statistical Analysis Plan
Not applicable
Informed Consent Form

Undecided - It is not yet known if there will be a plan to
make this available
Clinical Study Report
Not applicable
Analytic Code
Not applicable
Data Dictionary
Not applicable