Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 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)

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+98 28 3333 6001

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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

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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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Full name of responsible person
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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
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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