

Clinical Trial Protocol

Iranian Registry of Clinical Trials

28 May 2026

Effect of milk thistle (Silymarin marianum) extract supplementation on nonalcoholic fatty liver disease in morbidly-obese patient candidates for bariatric surgery

Protocol summary

Study aim

Effect of Silymarin supplementation on non-alcoholic fatty liver disease (NAFLD) in morbidly-obese patient candidates for bariatric surgery.

Design

A controlled clinical trial with parallel, double-blind, randomized groups on 50 obese patients who are candidates for bariatric surgery and are awaiting preoperative counseling and treatment.

Settings and conduct

Patients will be contacted biweekly to insure compliance with the lifestyle modification and Silymarin supplementation regime. Silymarin is produced in Iran, with the name liverhealth G 140 mg. life style modification is a 500 kcal.day-1 deficit from their normal weight-maintaining caloric intake.

Participants/Inclusion and exclusion criteria

Patients aged between 18 and 65 years .Diagnosis of NAFLD in liver sonography (grades II and III steatosis) with increased levels of liver enzymes aspartate transaminase (AST) and alanine transaminase (ALT) (above 20 mg/dl for women and 30 mg/dl for men) BMI above 40 kg/m² candidate for bariatric surgery

Intervention groups

Both groups will participate in eight weeks of lifestyle modification, which consisted of 500 kcal.day-1 deficit. Trial group Silymarin in tablet form, while the placebo group will take a placebo.

Main outcome variables

blood glucose, platelet count, aspartate aminotransferase, alanine aminotransferase, weight, albumin, liver sonography, liver fibrosis

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20210817052218N1**

Registration date: **2021-12-01, 1400/09/10**

Registration timing: **prospective**

Last update: **2021-12-01, 1400/09/10**

Update count: **0**

Registration date

2021-12-01, 1400/09/10

Registrant information

Name

Seyed Hadi Mirhashemi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 23871

Email address

sh.mirhashemi@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-12-16, 1400/09/25

Expected recruitment end date

2022-03-16, 1400/12/25

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of milk thistle (Silymarin marianum) extract supplementation on nonalcoholic fatty liver disease in

morbidly-obese patient candidates for bariatric surgery

Public title

Milk thistle (Silymarin marianum) extract supplementation on nonalcoholic fatty liver disease

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

patients aged between 18 and 65 years morbidly-obese patients candidates for bariatric surgery , BMI above 40 kg/m² Diagnosis of NAFLD in liver sonography (grades II and III steatosis) with increased levels of liver enzymes aspartate transaminase (AST) and alanine transaminase (ALT) (above 20 mg/dl for women and 30 mg/dl for men)

Exclusion criteria:

history of alcohol consumption diabetes mellitus chronic liver disease use of drugs such as statin, fibrate, non-steroidal anti-inflammatory drugs (NSAIDs), positive results for tests of autoimmune hepatitis and virus markers (hepatitis B surface antigen, hepatitis C virus antibody) unwilling to participate in study

Age

From **18 years** old to **65 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser
- Data and Safety Monitoring Board

Sample size

Target sample size: **50**

Randomization (investigator's opinion)

Randomized

Randomization description

Random allocation of patients will be based on simple randomization and with the help of accepted methods of random sequence production based on the web. The randomizer.org site will be used by filling in the information on the number of patients, two target groups, assigning an equal number in each group, and selecting non-duplicate numbers in this plan. Based on the random sequence numbers generated at the site, patients will be divided into two groups of 25 people under intervention receiving both lifestyle modification and Silymarin and the placebo group, which will receive the lifestyle modification and a placebo.

Blinding (investigator's opinion)

Double blinded

Blinding description

The allocation will be concealed by using opaque, sealed envelopes that were consecutively numbered. Apart from the project coordinator, the patients, attending physicians, staff involved in the surgery clinics, 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 Shahid Beheshti University of Medical Sciences,

Street address

Velenjak

City

Tehran

Province

Tehran

Postal code

1985717443

Approval date

2021-03-06, 1399/12/16

Ethics committee reference number

IR.SBMU.MSP.REC.1399.771

Health conditions studied

1

Description of health condition studied

Morbid obesity and non alcoholic liver disease

ICD-10 code

E66

ICD-10 code description

Overweight and obesity

Primary outcomes

1

Description

aspartate aminotransferase/alanine aminotransferase ratio

Timepoint

before and after two months of treatment

Method of measurement

Blood sample

2

Description

BMI (body mass index)

Timepoint

before and after two months of treatment

Method of measurement

scale

3

Description

Non alcoholic fatty liver disease

Timepoint

before and after two months of treatment

Method of measurement

Sonography

4

Description

Liver fibrosis

Timepoint

before and after two months of treatment

Method of measurement

Fibroscan Metavir

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: 500 kcal.day deficit from their normal weight-maintaining caloric intake plus taking 140 mg of Silymarin in tablet form, four times daily, for a total of 560 mg for eight weeks,

Category

Treatment - Drugs

2

Description

Control group: 500 kcal.day deficit from their normal weight-maintaining caloric intake plus taking placebo in tablet form, four times daily, for eight weeks,

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Loghman Hakimhospital

Full name of responsible person

Seyed Hadi Mirhashemi

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Makhsos St, South Karegar Ave, Tehran, Iran

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Dr. Afshin Zarghi

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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

Shahid Beheshti 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

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Seyed Hadi Mirhashemi

Position

Associate professore

Latest degree

Subspecialist

Other areas of specialty/work

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Not applicable

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

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Not applicable

Title and more details about the data/document

Effect of milk thistle (Silymarin marianum) extract supplementation on nonalcoholic fatty liver disease in morbidly-obese patient candidates for bariatric surgery

When the data will become available and for how long

in 6 months

To whom data/document is available

Study runners

Under which criteria data/document could be used

coauthorship in data publishing

From where data/document is obtainable

bariatric surgery teams in iran

What processes are involved for a request to access data/document

Sending requests by emails

Comments