Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 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 producted 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 alchoholic liver diseade
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 alchoholic 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
Street address
Makhsoos St, South Karegar Ave, Tehran, Iran
City
Tehran
Province
Tehran
Postal code
1333625445
Phone
+98 21 5541 9005
Email
loghman.hospital@sbmu.ac.ir

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Shahid Beheshti University of Medical Sciences
Full name of responsible person
Dr. Afshin Zarghi
Street address
Velenjak St. , Shahid Chamran Highway, Tehran, Iran.
City
tehran
Province
Tehran
Postal code
1985717443
Phone
+98 21 23871
Email
info@sbmu.ac.ir
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
General Surgery
Street address
Bldg SBUM, Arabi Ave, Daneshjoo Blvd, Velenjak, Tehran, Iran
City
Tehran
Province
Tehran

Postal code
1985717443
Phone
+98 21 23871
Email
sh.mirhashemi@gmail.com

Person responsible for scientific inquiries

Contact
Name of organization / entity
Shahid Beheshti University of Medical Sciences
Full name of responsible person
Parviz Rezaee
Position
Residentof general surgery
Latest degree
Medical doctor
Other areas of specialty/work
General Surgery
Street address
Bldg SBUM, Arabi Ave, Daneshjoo Blvd, Velenjak, Tehran, Iran
City
Tehran
Province
Tehran
Postal code
1985717443
Phone
+98 21 23871
Email
dr.parvizrezaee@gmail.com

Person responsible for updating data

Contact
Name of organization / entity
Shahid Beheshti University of Medical Sciences
Full name of responsible person
Parviz Rezaee
Position
resident of general surgery
Latest degree
Medical doctor
Other areas of specialty/work
General Surgery
Street address
Velenjak St. , Shahid Chamran Highway , Tehran, Iran
City
Tehran
Province
Tehran
Postal code
1985717443
Phone
+98 21 23871
Email
dr.parvizrezaee@gmail.com

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