Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

Assessing the effect of liverpower supplement on liver function in patients with fatty liver comparing to placebo

Protocol summary

Study aim
Determining the effect of liverpower capsules on improving liver function in patients with fatty liver compared to placbo

Design
80 participants (no=40 per group) are randomly assigned to intervention and placebo group using random digit table

Settings and conduct
This double blinded study will be performed in Fayaz Bakhsh Hospital. At base line and after 12 weeks of intervention with supplement/placebo, liver function tests (ALT, AST, ALK-Ph) and lipid profile (T.Chol, LDL-c, HDL-c, TG) will be recorded.

Participants/Inclusion and exclusion criteria
Inclusion criteria: Liver function enzymes higher than normal level, Fatty liver diagnosis based on sonography, Age>18 years Willing to participate in the study
Exclusion criteria: having known kidney disease, having known heart disease, pregnancy or lactation

Intervention groups
Patients will receive 500 mg liverpower capsule or placebo three times daily for 12 weeks. Each capsule contains Silybum marianum, Cichorium intybus L, Solanum nigrum and Urtica dioic extract or maltodextrine in placebo group.

Main outcome variables
Liver function tests (ALT, AST, ALK-Ph)

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20140804018677N11**
Registration date: **2021-08-09, 1400/05/18**
Registration timing: **registered_while_recruiting**
Last update: **2021-08-09, 1400/05/18**
Update count: **0**

Registration date
2021-08-09, 1400/05/18

Registrant information

Name
soodeh razeghi Jahromi

Name of organization / entity
Tehran University of Medical Sciences

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Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2021-07-10, 1400/04/19

Expected recruitment end date
2022-01-09, 1400/10/19

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Assessing the effect of liverpower supplement on liver function in patients with fatty liver comparing to placebo

Public title
Effect of liverpower on liver function in fatty liver

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Liver function enzymes higher than normal level Fatty liver diagnosis based on sonography Age>18 years Willing to participate in the study

Exclusion criteria:

Having known kidney disease Having known heart disease Pregnancy or lactation

Age

From **18 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor

Sample size

Target sample size: **80**

Randomization (investigator's opinion)

Randomized

Randomization description

Block Randomization method is used to randomize the patients. For randomization, we will visit the www.sealedenvelope.com and use randomization tab to make a list considering the number of intervention groups, sample size, block size (4 is selected for current study). The prepared list that contains the pattern of patient allocation will be obtained and used. This site is designed in such a way that there is no limit on the number of groups for random allocation. According to the total number of samples required for the study, which is 80 patients (40 patients in the intervention group (A) and 40 patients in the control group (B)), 20 blocks with a volume of four includes two groups A and B will be randomly selected using the software, such as (ABAB) ، (BBAB)، (AABB)، (ABBA)، (BAAB .....(Then 80pockets (40 pockets containing paper containing A and 40 pockets containing B) will be prepared based on sample size. According to a list of blocks, a trained person outside of the research team will be set the row of pockets. After admission of each patient will be given a pocket and assigned to Group A (intervention) or B (control group), and the sample process will be performed sequentially until the end of completion of sample size.

Blinding (investigator's opinion)

Double blinded

Blinding description

It is a double blind study. A third person out of study team (clinic secretary) have the sequence of codes that provide the team with sealed pockets coded as A or B at the time of sampling. The following groups of people involved in the trial: participants, research team including principle investigator, data collectors, and outcome assessors will be blind. After analyzing the data investigators and outcome assessors will be unblinded about A and B group allocation to supplement and placebo. Patients in supplement and placebo groups will receive packages of similar capsules.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of research and technology deputy of Shahid Beheshti University of Medical Sciences

Street address

No. 7, West Arghavan Ave., Farahzadi Blvd., Qods Town

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1981619573

Approval date

2019-02-17, 1397/11/28

Ethics committee reference number

IR.SBMU.RETECH.REC.1397.1305

Health conditions studied

1

Description of health condition studied

Fatty liver

ICD-10 code

K76.0

ICD-10 code description

Fatty (change of) liver, not elsewhere classified

Primary outcomes

1

Description

Alanine Aminotransferase (ALT) enzyme

Timepoint

Baseline and at the end of the study

Method of measurement

Biochemical kits

2

Description

Aspartate transaminase (AST) enzyme

Timepoint

Baseline and at the end of the study

Method of measurement

Biochemical kits

3

Description
Alkaline phosphatase (Alk-ph) enzyme
Timepoint
Baseline and at the end of the study
Method of measurement
Biochemical kits

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Intervention group: liverpower (500 mg), Ghaem darou company, three times daily for12 weeks
Category
Treatment - Other

2

Description
Control group: Placebo contain maltodextrine, (500 mg), Ghaem darou company, three times daily for12 weeks
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Shahid Fayaz Bakhsh Hospital
Full name of responsible person
Soodeh Razeghi Jahromi
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Shahid Beheshti University of Medical Sciences
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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
Soodeh Razeghi Jahromi
Position
Associate Professor
Latest degree
Ph.D.
Other areas of specialty/work
Nutrition
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Person responsible for updating data

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

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

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

Title and more details about the data/document
All data would be available to public

When the data will become available and for how long
Starting 6 months after publication

To whom data/document is available
To all

Under which criteria data/document could be used
No other critaria

From where data/document is obtainable
Email to soodehrazeghi@gmail.com

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

Comments