

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

The effect of traditional medicine capsule based on purslane and chicory on oxidative stress Indicators and Lipid Profile in patients with fatty liver disorder

Protocol summary

Study aim

The aim of this study was to evaluate the effect of hepatobel capsule on fatty liver recovery by measuring lipid profile and oxidative stress indices.

Design

In this study, 60 patients with fatty liver are divided into two groups of drug and placebo (n= 30 in each group). Grouping is simple and random. This is a double-blind study. In this study, blood samples are taken from individuals before the intervention and after 6 weeks of taking the capsules. Then, lipid profiles and oxidative stress indicators in these individuals are examined

Settings and conduct

If the individuals agree to participate in the research, written consent will be obtained from them and their information will be recorded in the relevant questionnaire. After 12 hours of fasting blood sampling are taken from the patient. Biochemical tests related to liver parameters are measured. Then, patients with liver function disorders are randomly divided into two groups. One group is receiving hepatobel capsules and the other receiving the placebo. This is a double-blind study in which participants and statistical analyst do not know the groups. After completing the 6-week intervention, blood sampling was performed again and the biochemical factors were evaluated to evaluate the effect of hepatobel capsules.

Participants/Inclusion and exclusion criteria

Patients with hepatic impairment indicators are enrolled in the study. These patients should not have heart and kidney disease. If a participant becomes allergic to the capsule during the study or can not continue reading, exit from the study.

Intervention groups

The group receiving the drug: This group consume three capsules daily for 6 weeks. The group receiving the placebo: This group consume three capsules daily for 6

weeks.

Main outcome variables

Improved fatty liver

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20141027019705N3**

Registration date: **2020-09-21, 1399/06/31**

Registration timing: **registered_while_recruiting**

Last update: **2020-09-21, 1399/06/31**

Update count: **0**

Registration date

2020-09-21, 1399/06/31

Registrant information

Name

Mehdi Salehi

Name of organization / entity

Tehran University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 21 3331 8165

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-09-09, 1399/06/19

Expected recruitment end date

2020-11-09, 1399/08/19

Actual recruitment start date

empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
The effect of traditional medicine capsule based on purslane and chicory on oxidative stress Indicators and Lipid Profile in patients with fatty liver disorder

Public title
The effect of hepatobel capsules in the treatment of fatty liver

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
 Not having known heart disease Not having known kidney disease Having abnormal liver parameters Having aged 20 to 60 years.
Exclusion criteria:
 Unwilling to continue study Find sensitivity to hepatobel capsules

Age
From **20 years** old to **60 years** old

Gender
Both

Phase
3

Groups that have been masked

- Participant
- Data analyser

Sample size
Target sample size: **60**

Randomization (investigator's opinion)
Randomized

Randomization description
To assign individuals to two groups of drugs and placebo block randomization method,using Random allocation software, with 4, 6 and 8 block sizes will be used, which by using this method, concealment will also be observed. In this method, each person is assigned a unique code and pasted on the drug packages, which will also help the blinding process.

Blinding (investigator's opinion)
Double blinded

Blinding description
First, it will be explained about the study to the participants. This study is a double blind study. The two groups of drug and placebo receive very similar capsules, and they do not know the contents of the capsule The statistical analyzer is not informed about the groups..

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Arak University of Medical Sciences

Street address

Iran, Arak, Sardasht, Basij Square, near Amiral-Momenin Hospital

City

Arak

Province

Markazi

Postal code

3848176341

Approval date

2020-02-15, 1398/11/26

Ethics committee reference number

IR.ARAKMU.REC.1398.316

Health conditions studied

1

Description of health condition studied

Patients with fatty liver

ICD-10 code

K76.0

ICD-10 code description

Fatty (change of) liver, not elsewhere classified

Primary outcomes

1

Description

Improving liver function

Timepoint

Measurement of lipid profile and oxidative stress indices in the beginning of the study (before the start of the study) and 6 weeks after the intervention

Method of measurement

Measuring lipid profile and oxidative stress indices using biochemical kits.

Secondary outcomes

1

Description

Improving lipid profile

Timepoint

Measurement of lipid profile in the beginning of the study (before the start of the study) and 6 weeks after the intervention

Method of measurement

Measuring lipid profile using biochemical kits.

2

Description

Improving oxidative stress indices

Timepoint

Measurement of oxidative stress in the beginning of the study (before the start of the study) and 6 weeks after the intervention

Method of measurement

Measuring oxidative stress using biochemical kits.

Intervention groups

1

Description

Intervention group: The number of participants in this group is 30 subjects. The group will receive 3 capsules of traditional medicine based on portulaca oleracea and Cichorium intybus (500 mg) daily for 6 weeks. This capsule is made by Sanabel Drug Company.

Category

Treatment - Drugs

2

Description

Control group: This group received 3 placebo capsules (500 mg) daily for 6 weeks. This capsule is made by Sanabel Drug Company.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Kowsar Clinic

Full name of responsible person

Mehdi Salehi

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Imam Street, Kowsar Clinic

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Arak University of Medical Sciences

Full name of responsible person

Alireza Kamali

Street address

Sardasht, Basij Square, near Amiral-Momenin Hospital

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research@arakmu.ac.ir

Grant name

Grant code / Reference number

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

No

Title of funding source

Arak 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

Arak University of Medical Sciences

Full name of responsible person

Mehdi Salehi

Position

Assistant professor

Latest degree

Ph.D.

Other areas of specialty/work

Traditional Medicine

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Person responsible for scientific inquiries

Contact

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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

Information from people participating in a study based on ethics should remain confidential.

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

No - There is not a plan to make this available

Analytic Code

Not applicable

Data Dictionary

Not applicable