

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

The effect of hepatobel on fatty liver parameters in patients with fatty liver disorder

Protocol summary

Study aim

The aim of this study was to evaluate the effect of hepatobel capsules on the improvement of fatty liver by measuring fatty liver indices.

Design

In this study, 60 patients with fatty liver are divided into two groups of drug and placebo (n= 30 in each group). Partitioning is simple and random. This is a double-blind study. In this study, before the intervention and after 6 weeks, the blood sample is taken from people and fatty liver parameters are studied in these subjects.

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

Main outcome variables

Improved fatty liver

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20141027019705N2**

Registration date: **2019-06-16, 1398/03/26**

Registration timing: **prospective**

Last update: **2019-06-16, 1398/03/26**

Update count: **0**

Registration date

2019-06-16, 1398/03/26

Registrant information

Name

Mehdi Salehi

Name of organization / entity

Tehran University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 21 3331 8165

Email address

m_salehi@razi.tums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-07-10, 1398/04/19

Expected recruitment end date

2019-08-10, 1398/05/19

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of hepatobel on fatty liver parameters in patients with fatty liver disorder

Public title

The effect of hepatobel on fatty liver

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Not having known heart disease Not having known kidney disease Having abnormal liver parameters

Exclusion criteria:

Unwilling to continue study Find sensitivity to hepatobel capsules

Age

No age limit

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Outcome assessor

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

The present study is a simple randomized clinical trial on subjects with fatty liver. In this study, individuals are divided into two groups of drugs and placebo. The method of assigning subjects to each group is that individuals are assigned one by one to each group.

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

2019-05-04, 1398/02/14

Ethics committee reference number

IR.ARAKMU.REC.1398.38

Health conditions studied

1

Description of health condition studied

Patients with fatty liver

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Improve liver function

Timepoint

Measurement of fatty liver enzymes in the beginning of the study (before the start of the study) and 6 weeks after the intervention

Method of measurement

Measuring liver enzymes using biochemical kits.

2

Description

Normalizing Fatty Liver Indices (such as FLI and HSI Indicators)

Timepoint

Measurement of fatty liver indices in the beginning of the study (before the start of the study) and 6 weeks after the intervention.

Method of measurement

Measuring liver enzymes using biochemical kits.

Secondary outcomes

1

Description

Improve blood sugar

Timepoint

Measurement of blood sugar in the beginning of the study (before the start of the study) and 6 weeks after the intervention

Method of measurement

Measuring blood sugar using biochemical kits.

2

Description

Improve blood bilirubin

Timepoint

Measurement of blood bilirubin in the beginning of the study (before the start of the study) and 6 weeks after the intervention

Method of measurement

Measuring blood bilirubin using biochemical kits.

Intervention groups

1

Description

Intervention group: The number of participants in this group is 30. The group has a fatty liver that receives hepatobel capsules for 6 weeks.

Category

Treatment - Drugs

2

Description

Control group: The number of participants in this group is 30. The group has a fatty liver that receives placebo capsules for 6 weeks.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Kowsar Clinic

Full name of responsible person

Mehdi Salehi

Street address

Sardasht, Basij Square, near Amiral-Momenin Hospital

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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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Grant name

Grant code / Reference number

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

Yes

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

Name of organization / entity

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Full name of responsible person

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Person responsible for updating data

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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

No - There is not a plan to make this available

Data Dictionary

Not applicable