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
City
Arak
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3848176341
Phone
+98 86 3417 3645
Email
m_salehi@razi.tums.ac.ir

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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Sardasht, Basij Square, near Amiral-Momenin Hospital
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Person responsible for scientific inquiries

Contact
Name of organization / entity

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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 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