

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

Formulation and evaluation of the effectiveness of "Berberpim®" syrup in patients with Non-alcoholic fatty liver disease: A randomized clinical trial study

Protocol summary

Study aim

The aim of this study was to prescribe "Berberpim®" syrup to patients with Non-alcoholic fatty liver disease and evaluate its effectiveness in a randomized, double-blind, placebo-controlled clinical trial.

Design

In this study, 46 patients were randomly assigned to take "Berberpim®" syrup (intervention) or placebo (control) for 3 months. In this way, 10 cc of syrup is used twice daily.

Settings and conduct

This study was performed randomly on 46 patients including intervention and control groups in Ejlalieh Clinic of Kermanshah University of Medical Sciences. In this way, 10 cc of syrup is used twice daily. Blinding is performed for patients, clinical caregivers and outcome assessors. Randomization is also done using blocks of 4 and 6.

Participants/Inclusion and exclusion criteria

The main inclusion criteria are the following: age over 18 years; patients to sign a written consent and have the necessary cooperation during the study and patients who have the disease according to the results of ultrasound, clinical interview, increase in liver enzymes. Main exclusion criteria also include: patients with Hepatitis; Wilson's disease; people who drink alcohol; people with type I diabetes and type II diabetes who have been taking drugs for a year and people taking drugs that affect the level of liver enzymes such as Statins and Acetaminophen in high doses.

Intervention groups

Intervention: Twice daily oral administration of 10 cc of "Berberpim®" syrup for 3 months Control: Twice daily oral administration of 10 cc of placebo syrup for 3 months

Main outcome variables

Biochemical factors (serum levels of CRP; ESR; LDL; HDL;

ALT; AST; triglycerides; cholesterol; platelets; vitamin D; fasting blood sugar) and anthropometric factors (BMI; weight and abdominal circumference)

General information

Reason for update

Due to the need to determine the grade of the disease as one of the criteria for inclusion in the study and change of the disease center, the mentioned cases were corrected.

Acronym

IRCT registration information

IRCT registration number: **IRCT20210814052178N1**

Registration date: **2021-09-02, 1400/06/11**

Registration timing: **prospective**

Last update: **2021-11-01, 1400/08/10**

Update count: **1**

Registration date

2021-09-02, 1400/06/11

Registrant information

Name

Kiana Anboohgol

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 83 3720 0622

Email address

kanboohgol@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-11-06, 1400/08/15

Expected recruitment end date

2022-05-05, 1401/02/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Formulation and evaluation of the effectiveness of "Berberpim®" syrup in patients with Non-alcoholic fatty liver disease: A randomized clinical trial study

Public title

The effect of "Berberpim®" syrup on Non-alcoholic fatty liver disease

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Age over 18 years Patients with grade I and II Non-alcoholic fatty liver disease according to the results of ultrasound, clinical interview, increase in liver enzymes and elimination of other causes this disease affects Non-alcoholic fatty liver

Exclusion criteria:

Patients with Hepatitis Wilson's disease People who drink alcohol People with type I diabetes and type II diabetes who have been taking the drug for a year Consumers of drugs that affect the level of liver enzymes such as Statins and Acetaminophen in high doses

Age

From **18 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser

Sample size

Target sample size: **46**

Randomization (investigator's opinion)

Randomized

Randomization description

In this study, two groups that meet the inclusion criteria are randomly assigned to the drug and placebo groups. Randomization process is done using 4 and 6 blocks. Blocking will be done by online randomization software www.sealedenvelope.com

Blinding (investigator's opinion)

Double blinded

Blinding description

The double-blind method is used for blinding. The list of intervention groups identified in this process remains with the coordinator. The person responsible for evaluating the entry / exit criteria and registration of

individuals will not be aware of this process. None of the patients and the evaluator will know the type of treatment

Placebo

Used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics committee of Kermanshah University of Medical Sciences

Street address

School of Pharmacy, Kermanshah University of Medical Sciences, Daneshgah St., Shahid Shiroodi Blvd., Kermanshah

City

Kermanshah

Province

Kermanshah

Postal code

6715847141

Approval date

2021-10-19, 1400/07/27

Ethics committee reference number

IR.KUMS.REC.1400.543

Health conditions studied**1****Description of health condition studied**

Non-alcoholic fatty liver disease

ICD-10 code

K76.0

ICD-10 code description

Fatty (change of) liver, not elsewhere classified

Primary outcomes**1****Description**

Alanine transaminase

Timepoint

Before intervention, 3 months after intervention

Method of measurement

Blood Test

2**Description**

Aspartate transaminase

Timepoint

Before intervention, 3 months after intervention

Method of measurement

Blood Test

3**Description**

Triglyceride

Timepoint

Before intervention, 3 months after intervention

Method of measurement

Blood Test

4**Description**

Cholesterol

Timepoint

Before intervention, 3 months after intervention

Method of measurement

Blood Test

5**Description**

High-density lipoprotein

Timepoint

Before intervention, 3 months after intervention

Method of measurement

Blood Test

6**Description**

Low-density lipoprotein

Timepoint

Before intervention, 3 months after intervention

Method of measurement

Blood Test

7**Description**

Fasting blood sugar

Timepoint

Before intervention, 3 months after intervention

Method of measurement

Blood Test

8**Description**

Platelets

Timepoint

Before intervention, 3 months after intervention

Method of measurement

Blood Test

9**Description**

Vitamin D

Timepoint

Before intervention, 3 months after intervention

Method of measurement

Blood Test

10**Description**

C-Reactive Protein

Timepoint

Before intervention, 3 months after intervention

Method of measurement

Blood Test

11**Description**

Erythrocyte Sedimentation Rate

Timepoint

Before intervention, 3 months after intervention

Method of measurement

Blood Test

12**Description**

Weight

Timepoint

Before intervention, 3 months after intervention

Method of measurement

Weighing scales

13**Description**

Abdominal circumference

Timepoint

Before intervention, 3 months after intervention

Method of measurement

Tapeline

14**Description**

Body mass index

Timepoint

Before intervention, 3 months after intervention

Method of measurement

Special formula

Secondary outcomes

empty

Intervention groups**1****Description**

Intervention group: Twice daily use 10 cc of Berberpim syrup to move for 3 months

Category

Treatment - Drugs

2

Description

Control group: Twice daily use of 10 cc placebo for 3 months

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Ejlalieh Clinic of Kermanshah

Full name of responsible person

DR. Mohammad Hossein Farzaei

Street address

Kermanshah, West Moallem Street, Parking Shahrdari

City

Kermanshah

Province

Kermanshah

Postal code

6714694451

Phone

+98 83 3728 4242

Email

mh-farzaee@razi.tums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Kermanshah University of Medical Sciences

Full name of responsible person

Dr. Mohammad Hossein Farzaei

Street address

Kermanshah, Shahid Shiroodi Blvd., Daneshgah St.,
Faculty of Pharmacy, Kermanshah University of
Medical Sciences

City

Kermanshah

Province

Kermanshah

Postal code

6743667149

Phone

+98 83 3428 1374

Email

mh-farzaee@razi.tums.ac.ir

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Kermanshah 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

Kermanshah University of Medical Sciences

Full name of responsible person

Kiana Anboohgol

Position

دانشجوی دکترای حرفه ای داروسازی

Latest degree

Medical doctor

Other areas of specialty/work

Medical Pharmacy

Street address

Kermanshah, Shahid Shiroodi Blvd., Daneshgah St.,
Faculty of Pharmacy, Kermanshah University of
Medical Sciences

City

Kermanshah

Province

Kermanshah

Postal code

6714694451

Phone

+98 35 24402

Email

Kanboohgol@yahoo.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

Kermanshah University of Medical Sciences

Full name of responsible person

Dr. Mohammad Hossein Farzaei

Position

Associate Professor

Latest degree

Specialist

Other areas of specialty/work

Medical Pharmacy

Street address

Kermanshah, Shahid Shiroodi Blvd., Daneshgah St.,
Faculty of Pharmacy, Kermanshah University of
Medical Sciences

City

Kermanshah

Province

Kermanshah

Postal code

6714694451

Phone

+98 35 24402

Email

mh-farzaee@razi.tums.ac.ir

Phone

+98 35 24402

Email

Kanboohgol@yahoo.com

Person responsible for updating data**Contact****Name of organization / entity**

Kermanshah University of Medical Sciences

Full name of responsible person

Kiana Anboohgol

Position

Professional doctorate student in Pharmacy

Latest degree

Medical doctor

Other areas of specialty/work

Medical Pharmacy

Street address

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Province

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Postal code

6714694451

Sharing plan**Deidentified Individual Participant Data Set (IPD)**

Undecided - It is not yet known if there will be 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