

Clinical Trial Protocol

Iranian Registry of Clinical Trials

22 Jul 2026

A randomized, double-blind, placebo-controlled trial evaluating the effect of Morus nigra extract on patients with liver cirrhosis

Protocol summary

Study aim

Evaluating the effect of Morus nigra extract on MELD (Model for End-stage Liver Disease) and Child-Pugh scores in patients with liver cirrhosis

Design

Clinical trial with a control group, parallel, double-blind, randomized, phase 2 on 80 patients (two groups of forty). The patients will be randomized into blocks; the randomization sequence will generate using an online randomization service (www.randomization.com).

Settings and conduct

The patients with liver cirrhosis will be randomized by block randomization method into 2 groups. In the intervention group, patients will receive capsules containing Morus nigra fruit extract (two 500 mg capsules, three times daily) orally for 12 weeks. Subjects in the placebo group will receive two 500 mg capsules orally containing microcrystalline cellulose, three times a day for 12 weeks. In addition to patients, physicians and individuals who perform serum biochemical tests and liver ultrasounds are blinded. Only the person responsible for randomizing and analyzing the results knows about grouping.

Participants/Inclusion and exclusion criteria

Inclusion criteria: patients with liver cirrhosis awaiting liver transplantation. Exclusion criteria: Hepatocellular carcinoma or other malignancy, history of liver transplantation, alcoholic drink, variceal bleeding, portal vein thrombosis, and pregnancy.

Intervention groups

The treatment group will receive capsules containing Morus nigra extract (two 500 mg capsules, three times daily) for 12 weeks. Subjects in the placebo group will receive capsules containing microcrystalline cellulose (Avicel) with the same schedule.

Main outcome variables

MELD index (Model for End-stage Liver Disease)

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20140301016776N3**

Registration date: **2021-06-15, 1400/03/25**

Registration timing: **prospective**

Last update: **2021-06-15, 1400/03/25**

Update count: **0**

Registration date

2021-06-15, 1400/03/25

Registrant information

Name

Ahmad Ghorbani

Name of organization / entity

Mashhad University of Medical Sciences

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-10-23, 1400/08/01

Expected recruitment end date

2023-04-21, 1402/02/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

A randomized, double-blind, placebo-controlled trial evaluating the effect of Morus nigra extract on patients with liver cirrhosis

Public title

The effect of Morus nigra extract on patients with liver cirrhosis

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Patients with liver cirrhosis awaiting liver transplantation

Exclusion criteria:

Hepatocellular carcinoma or other malignancy History of liver transplantation Alcoholic drink Variceal bleeding Portal vein thrombosis Pregnancy

Age

From **18 years** old to **75 years** old

Gender

Both

Phase

2-3

Groups that have been masked

- Participant
- Investigator
- Outcome assessor

Sample size

Target sample size: **80**

Randomization (investigator's opinion)

Randomized

Randomization description

In order to balance the number of patients in the two groups (A and B), the block randomization method will be used. After confirming the inclusion criteria and obtaining consent, patients are randomized by the research assistant based on blocks with size 4 or 6 . According to the sample size of 80 participants, 8 blocks with size 4 from AABB, ABAB, ABBA, BABA, BBAA, BAAB and 8 with size 6 from AAABBB, BBBAAA, BAAABB, BAABBA, BBAAAB, ABBABA, BABBA, ABBAAB, BBABAA, are selected using a random number table. The sealed envelope will be used for randomization.

Blinding (investigator's opinion)

Double blinded

Blinding description

Packages containing drug and placebo capsules are marked A and B. After randomization of patients by the research assistant, the capsules are provided to the participants by the same assistant. Two groups of participants (intervention patients and control patients) and researchers evaluating patients (serum biochemical factors and liver ultrasound) are not aware of grouping.

Placebo

Used

Assignment

Parallel

Other design features**Secondary Ids**

empty

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

Ethics committee of Mashhad University of Medical Sciences

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Qoreyshi building - Daneshgah street

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Mashhad

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Razavi Khorasan

Postal code

9138813944

Approval date

2021-01-27, 1399/11/08

Ethics committee reference number

IR.MUMS.MEDICAL.REC.1399.817

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

Liver cirrhosis

ICD-10 code

K74

ICD-10 code description

Fibrosis and cirrhosis of liver

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

MELD index.

Timepoint

Before intervention and end of the study.

Method of measurement

The MELD index is determined by total bilirubin, serum creatinine, and INR ($9.57 \ln(\text{Creat}) + 3.78 \ln(\text{bili}) + 11.2 \ln(\text{INR}) + 6.43$).

Secondary outcomes**1****Description**

Child-Pugh

Timepoint

before intervention and at the end of study

Method of measurement

This index is calculated based on total bilirubin, albumin, INR, ascites and encephalopathy.

2

Description

Patient survival

Timepoint

One year after enrollment.

Method of measurement

Record the number of patient deaths

3

Description

Liver enzymes

Timepoint

Before intervention and at the end of study

Method of measurement

Fasting blood test

Intervention groups

1

Description

Intervention group: In this group, patients will receive capsules containing Morus nigra fruit extract (two 500 mg capsules, three times daily) orally for 12 weeks.

Category

Treatment - Drugs

2

Description

Control group: Subjects in the placebo group will receive capsules containing microcrystalline cellulose (two 500 mg capsules, three times daily) orally for 12 weeks.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Ghaem Educational Research and Treatment Center

Full name of responsible person

Dr. Mitra Ahadi

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Sponsors / Funding sources

1

Sponsor

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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

Mashhad 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

Mashhad University of Medical Sciences

Full name of responsible person

Ahmad Ghorbani

Position

Associate professor

Latest degree

Ph.D.

Other areas of specialty/work

Physiology

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Not applicable

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Not applicable

Data Dictionary

Not applicable

Title and more details about the data/document

Study data including results related to primary and secondary outcomes after statistical analysis can be shared.

When the data will become available and for how long

starting 6 months after publication

To whom data/document is available

Available for people working in academic institutions

Under which criteria data/document could be used

Sharing of study data is subject to permission of Mashhad University of Medical Sciences.

From where data/document is obtainable

Applicants can contact the principle Investigator via email.

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

Sharing of study data is subject to permission of Mashhad University of Medical Sciences.

Comments