

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

01 Jun 2026

### Evaluation of therapeutic effects of a Panica granatum preparation in patients with hepatic cirrhosis using a randomized clinical trial

#### Protocol summary

##### Study aim

Determination of effect of a pomegranate preparation in patients with liver cirrhosis

##### Design

Clinical trial with control group, with parallel group, double blind, randomized

##### Settings and conduct

This study is in the field of herbal medicines. In a clinical trial, an herbal preparation of pomegranate was administered to 70 patients with liver cirrhosis in Ghaem hospital, Mashhad University of Medical Sciences. The patients were randomly divided to two groups (35 in each). A group will be given the pomegranate preparation and the other group is given the placebo. In this double blind trial, Participants, clinicians and evaluators will be unaware of intervention and control groups. A number of blood tests including AST, ALT, ALP, Albumin, creatinine, bilirubin, international normalized ratio for pro thrombintime (INR), for MELD factor (Model for End-Stage Liver Disease) calculation as well as also clinical investigations for presence of ascites and hepatic encephalopathy are done before and after the intervention.

##### Participants/Inclusion and exclusion criteria

Patients with liver cirrhosis (Hepatic cirrhosis)

##### Intervention groups

In Intervention group, a herbal preparation of pomegranate in patients with liver cirrhosis is given. In control group, a preparation without pomegranate (placebo) is given

##### Main outcome variables

ALT (Alanin Transaminase), AST (Aspartate Aminotransferase), ALP ( Alkaline Phosphatase), INR ( International Normalized Ratio), Albumin, creatinine, bilirubin, also clinical investigations for presence of ascites and hepatic encephalopathy and calculation of MELD score Model for End-Stage Liver Disease

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20191130045548N1**

Registration date: **2020-07-28, 1399/05/07**

Registration timing: **prospective**

Last update: **2020-07-28, 1399/05/07**

Update count: **0**

##### Registration date

2020-07-28, 1399/05/07

##### Registrant information

##### Name

Arezoo Rajabian

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 51 3882 8886

##### Email address

rajabianar@mums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2020-09-22, 1399/07/01

##### Expected recruitment end date

2022-09-23, 1401/07/01

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Evaluation of therapeutic effects of a Panica granatum preparation in patients with hepatic cirrhosis using a randomized clinical trial

#### Public title

Evaluation of therapeutic effects of a pomegranate preparation in patients with hepatic cirrhosis

#### Purpose

Treatment

#### Inclusion/Exclusion criteria

##### Inclusion criteria:

Patients with hepatic cirrhosis

##### Exclusion criteria:

Non-cirrhotic patients Cirrhotic patients who have progressed to liver transplantation

#### Age

From **18 years** old to **70 years** old

#### Gender

Both

#### Phase

2

#### Groups that have been masked

- Participant
- Care provider
- Investigator

#### Sample size

Target sample size: **70**

#### Randomization (investigator's opinion)

Randomized

#### Randomization description

The method of randomization is as block randomization and randomization unit is block (4-units block). The randomization tool and random sequence generation are done using random number table and through <http://www.randomization.com>. We have two groups in our study (indicated as A and B letters). Therefore, for random blocks, 6 modes of moving them are possible and the below formula is used. Also, the method of allocation concealment is equentially numbered, sealed, opaque envelopes. 6  
$$\text{modes} = 2.4 \times 3 = \frac{2! \times 4! \times [(2 \times 1)! \times 2]}{(4 \times 3 \times 2 \times 1 \times 1)!} \times 4$$

#### Blinding (investigator's opinion)

Double blinded

#### Blinding description

The blinding is as double in this study. For proper blinding, the drug (in our study, the herbal preparation from pomegranate) and placebo will be exactly the same in color, size, and odor, and other than the pharmacist, none of the participants and researchers will be aware of them until the end of the study.

#### 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

##### Street address

Vakilabad Blvd., Azadi St., Mashhad Town

##### City

Mashhad

##### Province

Razavi Khorasan

##### Postal code

9177948564

#### Approval date

2020-06-28, 1399/04/08

#### Ethics committee reference number

IR.MUMS.MEDICAL.REC.1399.121

## Health conditions studied

### 1

#### Description of health condition studied

liver cirrhosis

#### ICD-10 code

K74.69

#### ICD-10 code description

Other cirrhosis of liver

## Primary outcomes

### 1

#### Description

Model for End-Stage Liver Disease (MELD) score

#### Timepoint

The beginning of the study (or before administration of pomegranate preparation) and two months after (two months after administration of the preparation)

#### Method of measurement

ALT (Alanin Transaminase), AST (Aspartate Aminotransferase), ALP ( Alkaline Phosphatase), INR ( International Normalized Ratio), Albumin, creatinine, bilirubin, also clinical investigations for presence of ascites and hepatic encephalopathy and calculation of MELD score Model for End-Stage Liver Disease

## Secondary outcomes

empty

## Intervention groups

### 1

#### Description

Intervention group: In this group, an herbal preparation of pomegranate at 20 mg/kg body weight, is orally given twice in a day for 2 months to the patients with liver

cirrhosis. This study is done as double blind with 70 patients who randomly assigned in two groups (35 patients in each) and other than the pharmacist, none of the participants and researchers will be aware of the administrated drug and placebo until the end of the study. Therefore, 35 patients with cirrhosis is given the drug, randomly. A number of blood tests including AST, ALT, ALP, Albumin, creatinine, bilirubin, international normalized ratio for pro thrombintime (INR), for MELD factor (Model for End-Stage Liver Disease) calculation as well as also clinical investigations for presence of ascites and hepatic encephalopathy are done before and after the intervention for this intervention group.

#### Category

Treatment - Drugs

## 2

#### Description

Control group: In this group, a preparation without pomegranate (placebo) which is exactly the same in color, size, and odor with the drug is orally given twice in a day for 2 months to the patients with liver cirrhosis. This study is done as double blind with 70 patients who randomly assigned in two groups (35 patients in each) and other than the pharmacist, none of the participants and researchers will be aware of the administrated drug and placebo until the end of the study. Therefore, 35 patients with cirrhosis is given the placebo, randomly. A number of blood tests including AST, ALT, ALP, Albumin, creatinine, bilirubin, international normalized ratio for pro thrombintime (INR), for MELD factor (Model for End-Stage Liver Disease) calculation as well as also clinical investigations for presence of ascites and hepatic encephalopathy are done before and after the intervention for this intervention group

#### Category

Placebo

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Ghaem Hospital, Mashhad University of Medical Science

##### Full name of responsible person

Arezoo Rajabian

##### Street address

Vakilabad Ave., Mashhad city

##### City

Mashhad

##### Province

Razavi Khorasan

##### Postal code

9177948564

##### Phone

+98 51 3882 8265

##### Email

rajabianar@mums.ac.ir

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Mashhad University of Medical Sciences

##### Full name of responsible person

Mohsen Tafaghodi

##### Street address

Daneshgah st., Mashhad University of medical Science

##### City

Mashhad

##### Province

Razavi Khorasan

##### Postal code

9177948564

##### Phone

+98 51 3841 1538

##### Fax

+98 51 3882 3251

##### Email

tafaghodim@mums.ac.ir

#### 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

Arezoo Rajabian

##### Position

Pharmacologist, reseacher

##### Latest degree

Ph.D.

##### Other areas of specialty/work

Pharmacologist

##### Street address

Vakilabad st., Faculty of Medicine, Mashhad University of Medical Sciences

##### City

Mashhad

##### Province

Razavi Khorasan

**Postal code**

9177948564

**Phone**

0098 38828265

**Email**

rajabianar@mums.ac.ir

## Person responsible for scientific inquiries

**Contact**

**Name of organization / entity**

Mashhad University of Medical Sciences

**Full name of responsible person**

Arezoo Rajabian

**Position**

Clinical Pharmacologist, Researcher

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Clinical Pharmacologist

**Street address**

Vakilabad st., Faculty of Medicine, Mashhad  
University of Medical Sciences

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Mashhad

**Province**

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## Person responsible for updating data

**Contact**

**Name of organization / entity**

Mashhad University of Medical Sciences

**Full name of responsible person**

Arezoo Rajabian

**Position**

Clinical Pharmacologist, Researcher

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Pharmacology

**Street address**

Vakilaba

**City**

Mashhad

**Province**

Razavi Khorasan

**Postal code**

9177948564

**Phone**

+98 51 3882 8254

**Email**

rajabianar@mums.ac.ir

## 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**

There is no more information

**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**

No - There is not a plan to make this available