Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 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 medicnes. 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)

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+98 51 3882 8886

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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 modes=2.4*3=![2-4]*[(2*1)!2]/(4*3*2*1*)!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

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Mohsen Tafaghodi

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Daneshgah st., Mashhad University of medical Science

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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

Arezoo Rajabian

Position

Pharmacologist, reseacher

Latest degree

Ph.D.

Other areas of specialty/work

Pharmacologist

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Person responsible for scientific inquiries

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Full name of responsible person
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Position
Clinical Pharmacologist, Researcher

Latest degree
Ph.D.

Other areas of specialty/work
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Person responsible for updating data

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Ph.D.

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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
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