

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Sep 2026

Effect of Combination Therapy with Ledipasvir and Sofosbuvir (Hepasbuvir Plus) with or without Ribavirin for Treatment of Iranian Patients with Genotype-1 Hepatitis C Virus Infection

Protocol summary

Summary

This clinical trial study aims to evaluate the effect of combination therapy with ledipasvir and sofosbuvir (Hepasbuvir Plus) with or without ribavirin for treatment of Iranian patients with genotype-1 hepatitis C virus infection attending in clinics of Iran Hepatitis Network. Duration of treatment can be 12 or 24 weeks. Based on the presence or absence of cirrhosis and with consideration of related contraindications, patients can also receive Ribavirin. Finally after 12 weeks of end of treatment, overall response to therapy, effect of cirrhosis and history of previous treatment on response to therapy will be investigated.

General information

Acronym

HepCC-HCV2

IRCT registration information

IRCT registration number: **IRCT2016050717413N15**

Registration date: **2017-04-24, 1396/02/04**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2017-04-24, 1396/02/04

Registrant information

Name

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Name of organization / entity

Student Research Committee, Baqiyatallah University of Medical Sciences

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Baqiyatallah Research Center for Gastroenterology and Liver (BRCGL) Diseases. Baqiyatallah University of Medical Sciences, Tehran, IR Iran

Expected recruitment start date

2015-03-21, 1394/01/01

Expected recruitment end date

2016-12-20, 1395/09/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of Combination Therapy with Ledipasvir and Sofosbuvir (Hepasbuvir Plus) with or without Ribavirin for Treatment of Iranian Patients with Genotype-1 Hepatitis C Virus Infection

Public title

Effect of Combination Therapy with Ledipasvir and Sofosbuvir (Hepasbuvir Plus) for Treatment of Patients with Hepatitis C Infection

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion Criteria: Iranian patients with genotype-1 hepatitis C virus infection; with minimum age of 18 year old; with or without previous history of treatment (Peg-Interferon, Ribavirin, Protease inhibitors including: Telaprevir and Boceprevir); Compensated or

Decompensated Cirrhosis; Exclusion Criteria: Co-infection with HIV infection; Patients with thalassemia; Patients with hemophilia; Patients with history of chronic hemodialysis; patients with history of liver transplantation

Age

From **18 years** old

Gender

Both

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: **30**

Randomization (investigator's opinion)

N/A

Randomization description**Blinding (investigator's opinion)**

Not blinded

Blinding description**Placebo**

Not used

Assignment

Single

Other design features**Secondary Ids**

empty

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

Baqiyatallah University of Medical Sciences

Street address

Tehran, Vanak sq, Mollasadra Avenue, Baqiyatallah Hospital

City

Tehran

Postal code**Approval date**

2016-08-01, 1395/05/11

Ethics committee reference number

IR.BMSU.REC.1395.45

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

Chronic hepatitis C infection

ICD-10 code

B18.2

ICD-10 code description

Chronic viral hepatitis C

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

Hepatitis C Viral load

Timepoint

Before starting therapy, 4 weeks after starting therapy, end of therapy, 4 weeks after end of therapy, 12 weeks after end of therapy

Method of measurement

Quantitative viral load in laboratory

Secondary outcomes

empty

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

Treatment with daily single-dose of Hepasbuvir plus (400 mg sofosbuvir/90 mg ledipasvir) made in Danesh pharmaceutical developmental co. Ribavirin (200 mg) can be added to the treatment protocol (five or six capsules). Treatment length is 12 or 24-week.

Category

Treatment - Drugs

Recruitment centers**1****Recruitment center****Name of recruitment center**

Clinics of Iran Hepatitis Networks

Full name of responsible person

Mohammad Saeid Rezaee-Zavareh

Street address

Baqiyatallah Research Center for Gastroenterology and Liver Diseases, Baqiyatallah Hospital, Mollasadra Avenue

City

Tehran

Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Baqiyatallah Research Center for Gastroenterology and Liver Diseases, Baqiyatallah University of Med

Full name of responsible person

Seyed Moayed Alavian

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Tehran

Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
 Yes
Title of funding source
 Baqiyatallah Research Center for Gastroenterology and Liver Diseases, Baqiyatallah University of Med
Proportion provided by this source
 100
Public or private sector
 empty
Domestic or foreign origin
 empty
Category of foreign source of funding
 empty
Country of origin
Type of organization providing the funding
 empty

Person responsible for general inquiries

Contact

Name of organization / entity
 Baqiyatallah Research Center for Gastroenterology and Liver Diseases, Baqiyatallah University of Med
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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
 empty
Study Protocol
 empty
Statistical Analysis Plan
 empty
Informed Consent Form
 empty
Clinical Study Report
 empty
Analytic Code
 empty
Data Dictionary
 empty