Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 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 Ribavirn. 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

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

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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
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
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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