Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 2026

A prospective, interventional, multi-center trial to evaluate the Efficacy and Safety of Sofosbuvir-Velpatasvir for the treatment of Chronic Hepatitis C patients in Pakistan.

Protocol summary

Study aim
To evaluate the safety & efficacy of Sofosbuvir-Velpatasvir combination in real world setting in Pakistan. Further, this study aims to assess sustained virologic response at 12 weeks after the end of therapy.

Design
prospective, open label, single arm, intervention & multi center trial.

Settings and conduct
Study is to be conducted at Gastroenterology department in Jinnah Post-graduate Medical center Karachi, Jinnah Hospital Lahore, Gulab Devi Hospital Lahore, Hayatabad Medical Complex Peshawar, and Pakistan Institute of Medical Sciences, Islamabad, Pakistan. Hepatitis-C patients visiting gastroenterology department of the mentioned institutes would be enrolled after meeting selection criteria. Treatment naive or treatment experienced patients would be prescribed sofosbuvir-velpatasvir combination for 12 weeks as per physician's discretion. Patients would be followed at week 04, week 12 and week 24 of the baseline visit.

Participants/Inclusion and exclusion criteria
Inclusion Criteria: Subjects willing to undergo screening and sign informed consent. Male or female outpatients ≥18 years of age. Serologically and histologically proven CHC, detectable HCV RNA, elevated ALT, and compensated liver disease. Exclusion Criteria: Unable to give written informed consent. Pregnant and/or Nursing Women. Contraindicated to medicine or any of the component of prescribed therapy

Intervention groups
sofosbuvir 400 mg + Velpatasvir 100 mg combination

Main outcome variables
Primary Outcome: Sustained Virologic Response (SVR) assessed at week 24 from baseline visit through HCV-RNA PCR. Secondary Outcome: End of treatment response (ETR) would be assessed at week 12 from baseline visit through HCV-RNA PCR.

General information

Reason for update

Acronym
CAVES-IT

IRCT registration information
IRCT registration number: **IRCT20170614034526N4**
Registration date: **2019-03-28, 1398/01/08**
Registration timing: **retrospective**

Last update: **2020-01-07, 1398/10/17**
Update count: **1**

Registration date
2019-03-28, 1398/01/08

Registrant information

Name
Dr. Sharib Syed Muhammad

Name of organization / entity
Hilton Pharma Pvt Ltd

Country
Pakistan

Phone
(021) 111-123-000 Ext:428

Email address
sharibsyed@hiltonpharma.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2018-04-02, 1397/01/13

Expected recruitment end date
2018-06-30, 1397/04/09

Actual recruitment start date
empty

Actual recruitment end date
empty
Trial completion date
empty

Scientific title
A prospective, interventional, multi-center trial to evaluate the Efficacy and Safety of Sofosbuvir-Velpatasvir for the treatment of Chronic Hepatitis C patients in Pakistan.

Public title
Efficacy & Safety of Velpatasvir-Sofosbuvir combination in treatment of Hepatitis-C patients of Pakistan, Phase-IV Interventional Trial
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Subjects willing to undergo screening and sign informed consent Male or female outpatients ≥18 years of age Serologically and histologically proven CHC, detectable HCV RNA, elevated ALT, and compensated liver disease.
Exclusion criteria:
Unable to give written informed consent Pregnant and/or Nursing Women Contraindicated to medicine or any of the component of prescribed therapy
Age
From **18 years** old
Gender
Both

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **155**
Randomization (investigator's opinion)
Not randomized
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
Jinnah Postgraduate Medical Center
Street address
Rafiqui Shaheed Road, Near National Institute of Child Health (NICH,
City
Karachi
Postal code
75510
Approval date
2018-05-22, 1397/03/01
Ethics committee reference number
F.2-81-IRB/2018-GENL/7065/JPMC

Health conditions studied

1

Description of health condition studied
Chronic Hepatitis-C
ICD-10 code
B18.2
ICD-10 code description
Chronic viral hepatitis C

Primary outcomes

1

Description
Sustained Virologic Response (SVR)
Timepoint
Assessed at week 24 from the baseline visit or start of therapy
Method of measurement
HCV-RNA PCR

Secondary outcomes

1

Description
End of Treatment Response (ETR)
Timepoint
assessed at week 12 from baseline visit or start of therapy.
Method of measurement
HCV-RNA PCR

2

Description
Adverse Events or Serious Adverse Events
Timepoint
assessed at week 04, week 12 & week 24 follow-up visits.
Method of measurement
Clinical examination or history by study participants

Intervention groups

1

Description
Intervention group: Sofosbuvir 400 mg + Velpatasvir 100

mg once daily for 12 weeks

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
Jinnah Postgraduate Medical Center

Full name of responsible person
Dr. Nazish Butt

Street address
Rafiqui Shaheed Road, Near National Institute of Child Health (NICH,

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Phone
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Email
dr.nazishbutt@gmail.com

2

Recruitment center

Name of recruitment center
Hayatabad Medical Complex

Full name of responsible person
Dr. Muhammad Iltaf

Street address
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Peshawar

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25100

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+92 91 9217140

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driltaf414@gmail.com

3

Recruitment center

Name of recruitment center
Jinnah Hospital

Full name of responsible person
Dr. Atique Abu Bkr

Street address
Usmani Rd, Punjab University New Campus

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Lahore

Postal code
54550

Phone
+92 42 99231400

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doctorattique07@yahoo.com

4

Recruitment center

Name of recruitment center
Pakistan Institute of Medical Sciences

Full name of responsible person
Dr. Ali Mashhood

Street address
Ibn-e-Sina Rd, G-8/3 G 8/3 G-8

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Islamabad

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44080

Phone
+92 51 9261170

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mashood.ali74@gmail.com

5

Recruitment center

Name of recruitment center
Gulab Devi Hospital

Full name of responsible person
Prof. Dr. Zaheer Akhtar

Street address
Ferozepur Road, Nishter Town

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Lahore

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Hilton Pharma Pvt Ltd

Full name of responsible person
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8th Floor, Progressive Plaza, Beaumont road

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sharibsyed@hiltonpharma.com

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?
Yes

Title of funding source
Hilton Pharma Pvt Ltd

Proportion provided by this source

100

Public or private sector
Private

Domestic or foreign origin
Domestic

Category of foreign source of funding
empty

Country of origin

Type of organization providing the funding
Industry

Person responsible for general inquiries

Contact

Name of organization / entity
Jinnah Post graduate Medical Center

Full name of responsible person
Dr. Nazish Butt

Position
Sindh

Latest degree
Specialist

Other areas of specialty/work
Gastroenterology

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Person responsible for scientific inquiries

Contact

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Position
Associate Professor

Latest degree
Specialist

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Person responsible for updating data

Contact

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Full name of responsible person
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Position
Sr. Officer Clinical Research

Latest degree
Bachelor

Other areas of specialty/work
Clinical Research & Medical Affairs

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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
To maintain the participants' confidentiality, however data would be made available if Ethics committee and local regulatory bodies demands.

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

Trial results

Please tick if results have been published
Yes

Summary result posting date

2020-01-07, 1398/10/17

Table of baseline comparison

Participant flow diagram

Table of variable outcomes' results

Baseline characteristics in patients without cirrhosis and in patients with compensated cirrhosis

Table of adverse events

First publication date

2020-01-01, 1398/10/11

Abstract of published paper

Background In Pakistan, there is a paucity of published clinical data regarding the efficacy of sofosbuvir-velpatasvir in the management of patients with hepatitis C without cirrhosis or with compensated cirrhosis. Methods A prospective, open-label, multicenter, interventional trial was conducted in patients with hepatitis C without cirrhosis or with compensated cirrhosis. Hepatitis C patients without cirrhosis or with compensated cirrhosis were screened, and 133 patients were enrolled in the study. They received sofosbuvir 400 mg plus velpatasvir 100 mg combination once daily for 12 weeks. Patients were followed up for six months after the start of therapy. Hepatitis C viral load was assessed at baseline, at week 12, and after 24 weeks following the start of the treatment. The trial was prospectively registered with the Iranian Registry of Clinical Trials (IRCT) with the identification number IRCT20170614034526N4. Results Among enrolled patients, 79 were male, and 54 were female. Ninety-five (71.4%) patients were without cirrhosis, and 38 had compensated cirrhosis. Patients without cirrhosis had a mean age of 45.90 ±10.99 years, and patients with compensated cirrhosis had a mean age of 52.60 ±12.29 years. As per the intention-to-treat analysis, all patients without cirrhosis and 35 (92.1%) patients with compensated cirrhosis achieved undetectable viral load hepatitis C virus (HCV) ribonucleic acid (RNA) of <15 IU/mL at 12 weeks from the start of treatment. Eighty-six (90.5%) patients without cirrhosis achieved sustained virologic response 12 weeks after the end of therapy. Patients with compensated cirrhosis experienced more adverse events (31.5%) than patients without cirrhosis (20.15%). Conclusion Direct-acting antiviral therapy using sofosbuvir and velpatasvir combination is effective and safe in HCV patients without cirrhosis and patients with compensated cirrhosis.