

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 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

Rafiqi 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

Rafiqi Shaheed Road, Near National Institute of Child Health (NICH,

City

Karachi

Postal code

75510

Phone

+92 21 99201300

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

Phase 4 Hayatabad

City

Peshawar

Postal code

25100

Phone

+92 91 9217140

Email

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

City

Lahore

Postal code

54550

Phone

+92 42 99231400

Email

doctoratique07@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

City

Islamabad

Postal code

44080

Phone

+92 51 9261170

Email

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

City

Lahore

Postal code

54000

Phone

+92 42 99230247

Email

drzaheerakhtar@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Hilton Pharma Pvt Ltd

Full name of responsible person

Dr. Syed Muhammad Sharib

Street address

8th Floor, Progressive Plaza, Beaumont road

City

Karachi

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75580

Phone

+92 21 35072224

Email

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
Street address
Rafiqi Shaheed Road, Near National Institute of Child Health NICH
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Person responsible for scientific inquiries

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Position
Associate Professor
Latest degree
Specialist
Other areas of specialty/work
Gastroenterology
Street address
Rafiqi Shaheed Road, Near National Institute of Child Health (NICH,
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Trial results

Please tick if results have been published

Yes

Karachi
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75510
Phone
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dr.nazishbutt@gmail.com

Person responsible for updating data

Contact

Name of organization / entity
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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
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City
Karachi
Province
Sindh
Postal code
75580
Phone
+92 21 35072224
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sharibsyed@hiltonpharma.com

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

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.