

Clinical Trial Protocol

Iranian Registry of Clinical Trials

03 Jul 2026

Efficacy and tolerability of Sofosbuvir and Daclatasvir for treatment of Hepatitis C genotype 3 in patients undergoing hemodialysis- A Prospective interventional clinical trial

Protocol summary

Study aim

To evaluate Direct acting antiviral therapy in patients infected with HCV-genotype 3 who are on maintenance hemodialysis.

Design

Prospective, Two arm parallel, Open label, Non-randomized, single centered, Interventional Trial

Settings and conduct

Study was conducted in Dialysis center; HCV Unit of Jinnah Hospital Lahore, Pakistan. Ethics Committee approval was taken from Ethical review board of Allama Iqbal medical College/ Jinnah Hospital, Lahore. Patients with End stage kidney disease undergoing maintenance hemodialysis with detectable HCV-RNA via using PCR, meeting inclusion criteria were included in the study after getting written informed consent. Baseline vital signs and laboratory parameters were recorded and then patients were allocated to two treatment groups in 1:1 ratio. The groups were group 1: Daclatasvir 60 mg + Sofosbuvir 400 mg once daily for 12 weeks and group 2: Daclatasvir 60 mg per day and Sofosbuvir 400 mg 3 times / per week for 12 weeks. Patients were then followed-up at week 12 and week 24 from the start of therapy to determine the ETR and SVR respectively. Patients' laboratory parameters (CBC & LFT) were recorded at baseline, week 12 and week 24.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Male & Female (non-pregnant) 18 years and above aged patients. End stage renal diseased patients undergoing maintenance hemodialysis detected with HCV RNA by PCR. Non inclusion criteria: Patients having co-infection with HBV, HIV; Patients with decompensated cirrhosis and terminal illness; Patients hypersensitive to any of the ingredients of treatment drugs.

Intervention groups

Intervention group 1: Daclatasvir 60 mg + Sofosbuvir

400 mg once daily for 12 weeks. Intervention group 2: Daily Daclatasvir 60 mg and Sofosbuvir 400 mg 3 times / per week for 12 weeks

Main outcome variables

Primary outcomes: Sustained Virologic Response (SVR); Secondary Outcome: End of Treatment response (ETR)

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20170614034526N3**

Registration date: **2019-03-08, 1397/12/17**

Registration timing: **retrospective**

Last update: **2019-03-08, 1397/12/17**

Update count: **0**

Registration date

2019-03-08, 1397/12/17

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

2017-08-01, 1396/05/10

Expected recruitment end date

2017-08-31, 1396/06/09

Actual recruitment start date

2017-09-01, 1396/06/10

Actual recruitment end date

2017-09-23, 1396/07/01

Trial completion date

2018-04-30, 1397/02/10

Scientific title

Efficacy and tolerability of Sofosbuvir and Daclatasvir for treatment of Hepatitis C genotype 3 in patients undergoing hemodialysis- A Prospective interventional clinical trial

Public title

Sofosbuvir and Daclatasvir for treatment of Hepatitis-C in patients undergoing hemodialysis.

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Male & Female (non-pregnant) being at the age of 18 years and over End stage renal disease patients undergoing maintenance hemodialysis detected with HCV RNA by PCR.

Exclusion criteria:

Patients having co-infection with HBV, HIV. Patients with decompensated cirrhosis and terminal illness. Patients hypersensitive to any of the ingredients of treatment drugs.

Age

From **18 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **36**

Actual sample size reached: **36**

Randomization (investigator's opinion)

Not randomized

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

Not blinded

Blinding description**Placebo**

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

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

Ethical Review Board, Allama Iqbal medical College/ Jinnah Hospital, Lahore

Street address

Jinnah Hospital; Moulana Shabbir Ahmed Usmani Road, Faisal Town; Lahore

City

Lahore

Postal code

54550

Approval date

2017-07-20, 1396/04/29

Ethics committee reference number

39th/ ERB

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

Chronic Viral Hepatitis-C

ICD-10 code

B18.2

ICD-10 code description

Chronic viral hepatitis C

2**Description of health condition studied**

Chronic kidney disease, stage 5

ICD-10 code

N18.5

ICD-10 code description

Chronic kidney disease, stage 5

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

Sustained Virologic Response (SVR) assessed

Timepoint

24th week after start of treatment

Method of measurement

HCV RNA- PCR

Secondary outcomes**1****Description**

End of Treatment response (ETR)

Timepoint

12th week of start of treatment

Method of measurement

HCV RNA-PCR

Intervention groups

1

Description

Intervention group 1: Daclatasvir 60 mg + Sofosbuvir 400 mg once daily for 12 weeks.

Category

Treatment - Drugs

2

Description

Intervention group 2: Daclatasvir 60 mg per day and Sofosbuvir 400 mg 3 times / per week for 12 weeks

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Jinnah Hospital Lahore

Full name of responsible person

Prof. Dr. Shafiq Ur Rehman Cheema

Street address

Jinnah Hospital Moulana Shabbir Ahmed Usmani Road, Faisal Town Lahore

City

Lahore

Postal code

54550

Phone

+92 42 99231400

Email

shafiqcheema@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Jinnah Hospital, Lahore

Full name of responsible person

Prof. Dr. Shafiq Ur Rehman Cheema

Street address

Jinnah Hospital; Moulana Shabbir Ahmed Usmani Road; Faisal Town

City

Lahore

Postal code

54550

Phone

+92 42 99231400

Email

shafiqcheema@yahoo.com

Grant name

Grant code / Reference number

Is the source of funding the same sponsor

organization/entity?

Yes

Title of funding source

Jinnah Hospital, Lahore

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

Jinnah Hospital & Allama Iqbal Medical College, Lahore

Full name of responsible person

Prof. Dr. Shafiq Ur Rehman Cheema

Position

Professor

Latest degree

Specialist

Other areas of specialty/work

Nephrology

Street address

Jinnah Hospital; Moulana Shabbir Ahmed Usmani Road; Faisal Town

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Province

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shafiqcheema@yahoo.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

Jinnah Hospital & Allama Iqbal Medical College, Lahore

Full name of responsible person

Prof. Dr. Shafiq Ur Rehman Cheema

Position

Professor

Latest degree

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Other areas of specialty/work

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Person responsible for updating data**Contact****Name of organization / entity**Jinnah Hospital & Allama Iqbal Medical College,
Lahore**Full name of responsible person**

Prof. Dr. Shafiq Ur Rehman Cheema

Position

Professor

Latest degree

Specialist

Other areas of specialty/work

Nephrology

Street addressJinnah Hospital; Moulana Shabbir Ahmed Usmani
Road; Faisal Town**City****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

Data can be inspected by Institute Ethical review board for any reason, but public data sharing is not planned for this specific study..

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