Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 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 grous 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
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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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Person responsible for updating data

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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
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