Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 2026

Effectiveness of Sofosbuvir/Daclatasvir for Treatment of People Who Inject Drug with HCV Infection in a Community-based Setting

Protocol summary

Study aim

Evaluation of treatment efficacy and safety using 12-week regimen of Sofosbuvir, Daclatasvir in people who inject drug with HCV infection in a community-based setting

Design

Rostam 3 is an open label study of HCV new treatment in a group of PWID with HCV infection in a drop-in-center. This study aims to assess the adherence of this group to treatment and finally evaluate the treatment success to present a model for implementation of HCV treatment in community-based settings. The cases will be recruited from two cross-sectional (Rostam 1) and cohort (Rostam 2) studies which evaluate the prevalence and incidence of HCV in PWIDs.

Settings and conduct

The study will be conducted in Monadian Salamat drop-in centre, Kerman, Iran. For those PWID who are reluctant to come to the study site, our team will visit them in mobile van. This single arm clinical trial study will be conducted in 110 PWIDs infected with HCV confirmed with positive HCV RNA. Eligible PWIDs (from Rostam 1) who consented to participate in the study will be treated 12 weeks with daily oral Sofosbuvir 400mg/Daclatasvir 60mg and be followed up. Moreover, cases found to be HCV infected in Rostam 2 will be called to receive treatment in Rostam 3.

Participants/Inclusion and exclusion criteria

PWID with confirmed chronic HCV infection

Intervention groups

12 weeks of treatment with Sofosbuvir 400mg/Daclatasvir 60mg fixed dose combination

Main outcome variables

The main outcomes evaluated in this study are: 1. Treatment uptake: acceptance to receive Sofosbuvir/Daclatasvir treatment 2. Treatment adherence: completing the treatment course and receiving >80% of treatment doses 3. Sustained virologic response (SVR): Having negative result for HCV RNA, 12 weeks after treatment completion

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20170213032547N1**
Registration date: **2018-06-25, 1397/04/04**
Registration timing: **registered_while_recruiting**

Last update: **2019-05-28, 1398/03/07**
Update count: **3**

Registration date

2018-06-25, 1397/04/04

Registrant information

Name
Heidar Sharafi
Name of organization / entity
Iran Hepatitis Network
Country
Iran (Islamic Republic of)
Phone
+98 21 8894 5186
Email address
h.sharafi@meldcenter.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-06-10, 1397/03/20

Expected recruitment end date

2019-07-23, 1398/05/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date
empty

Scientific title
Effectiveness of Sofosbuvir/Daclatasvir for Treatment of People Who Inject Drug with HCV Infection in a Community-based Setting

Public title
Hepatitis C Treatment in a Community-based Setting
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Being male or female (including transgender) Being 18 years or older at the time of baseline interview Self-reported drug injection with verification for non-medical purposes in the past twelve months Having chronic infection of HCV as confirmed by HCV-RNA Having lived for at least six months in Kerman and have no plan to move out for another three months Having written informed consent to participate in the study Understanding the Farsi language
Exclusion criteria:
Cirrhosis HBV/HCV Coinfection Pregnant woman TB/HCV Coinfection eGFR<30 mL/min or chronic renal failure Drug-drug interactions
Age
From **18 years** old to **80 years** old
Gender
Both

Phase
3
Groups that have been masked
No information
Sample size
Target sample size: **110**
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
Ethics committee of Kerman University of Medical Sciences
Street address
Ibn sina St., Jahad Boulevard, Somayeh Cross road.
City
Kerman
Province
Kerman
Postal code
76169-13555
Approval date
2018-04-16, 1397/01/27
Ethics committee reference number
IR.KMU.REC.1396.2422

Health conditions studied

1

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

Primary outcomes

1

Description
Sustained Virologic Response
Timepoint
12 weeks after termination of treatment
Method of measurement
HCV RNA using sensitive RT-PCR

Secondary outcomes

1

Description
Treatment uptake
Timepoint
At the study entry
Method of measurement
Acceptance to be treated

2

Description
Treatment Adherence
Timepoint
12 weeks of treatment
Method of measurement
Pill count

Intervention groups

1

Description
Treatment with daily single-dose of Daclasfovir Shari® (400 mg Sofosbuvir/60 mg Daclatasvir) made in

Shari/Bakhtar Bioshimi Co (BBpharmaco) for 12 weeks.

Category
Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
Monadian Salamat drop-in centre

Full name of responsible person
Dr. Armita Shahesmaeili

Street address
Next to Boustan Talar-Sarasiab Sq.

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Kerman

Province
Kerman

Postal code
76169-13555

Phone
+98 34 3211 3012

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armita.shahesmaeili@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Kerman University of Medical Sciences

Full name of responsible person
Dr. Gholamreza Sepehri

Street address
Ibn sina St., Jahad Boulevard, Somayeh Cross road.

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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
Kerman University of Medical Sciences

Proportion provided by this source
10

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

2

Sponsor

Name of organization / entity
National Institute for Medical Research Development

Full name of responsible person
Reza Malekzadeh

Street address
Besat street

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Tehran

Province
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1419693111

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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
National Institute for Medical Research Development

Proportion provided by this source
90

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
Other

Person responsible for general inquiries

Contact

Name of organization / entity
Kerman University of Medical Sciences

Full name of responsible person
Dr. Armita Shahesmaeili

Position
Researcher

Latest degree
Ph.D.

Other areas of specialty/work
Epidemiology

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Person responsible for scientific inquiries

Contact
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University of California, San Francisco
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Person responsible for updating data

Contact
Name of organization / entity
Baqiyatallah Research Center for Gastroenterology and Liver Diseases
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Scientific Director
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Ph.D.
Other areas of specialty/work
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Tehran
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Email
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available
Study Protocol
Yes - There is a plan to make this available
Statistical Analysis Plan
Yes - There is a plan to make this available
Informed Consent Form
Yes - There is a plan to make this available
Clinical Study Report
Yes - There is a plan to make this available
Analytic Code
Yes - There is a plan to make this available
Data Dictionary
Yes - There is a plan to make this available
Title and more details about the data/document
All available deidentified individual participant data will be shared.
When the data will become available and for how long
After publication of study.
To whom data/document is available
Researchers in the field.
Under which criteria data/document could be used
No additional publication can be conducted based on the shared data.
From where data/document is obtainable
Corresponding author of publication.
What processes are involved for a request to access data/document
A written request through email.
Comments