

Clinical Trial Protocol

Iranian Registry of Clinical Trials

28 Jun 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 Daclatasvir 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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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Kerman University of Medical Sciences

Full name of responsible person

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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

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Province

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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

Name of organization / entity
University of California, San Francisco
Full name of responsible person
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Person responsible for updating data

Contact

Name of organization / entity
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Dr. Heidar Sharafi
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Latest degree
Ph.D.

Other areas of specialty/work
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Phone
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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