

Clinical Trial Protocol

Iranian Registry of Clinical Trials

05 Jul 2026

Evaluation of the Effectiveness of Direct-Acting Antiviral (DAA) Regimens in Patients with Hepatitis C: A Multicenter and Follow-up Analysis

Protocol summary

Study aim

Evaluating of the effect of new Direct acting antivirals on different genotypes of hepatitis C virus (HCV).

Design

A clinical trial with one intervention group design of 51 patients (phase 3).

Settings and conduct

The subjects were selected according to the inclusion criteria from patients with hepatitis C referred to Shahid Sadoughi Hospital in Yazd. Their hepatitis C disease had already been confirmed, and its genotype was determined by Polymerase Chain Reaction (PCR). In this study, therapeutic DAA regimen prescribed for the treatment of the patients with GT3 virus was SOF 400 mg + DCV 60 mg. For the other GT cases, it was SOF 400 mg + LDV 90. According to the recommended instructions, the drugs were taken on an outpatient basis every day.

Participants/Inclusion and exclusion criteria

Inclusion criteria: 1- Adults (≥ 18 years) 2-regardless of their previous treatment or stage of liver fibrosis.

Exclusion criteria: 1- The patients who took drugs including carbamazepine, phenytoin, rifampin, phenobarbital, antacids and rosuvastatin. 2- had a history of taking amiodarone in the past three months. 3- those with severe renal insufficiency. 4- pregnant women. 5- patients with no high life expectancy due to other diseases were excluded from the study.

Intervention groups

In this study, therapeutic regimen prescribed for the treatment of the patients with GT3 virus was SOF 400 mg + DCV 60 mg. For the other GT cases, it was SOF 400 mg + LDV 90. According to the recommended instructions, the drugs were taken on an outpatient basis every day

Main outcome variables

Sustained Virological Response 12

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20081110001444N7**

Registration date: **2022-02-24, 1400/12/05**

Registration timing: **registered_while_recruiting**

Last update: **2022-02-24, 1400/12/05**

Update count: **0**

Registration date

2022-02-24, 1400/12/05

Registrant information

Name

mohsen akhondi meybodi

Name of organization / entity

Shahid Sadoughi University of Medical Sciences-Yazd, Iran

Country

Iran (Islamic Republic of)

Phone

+98 35 1822 5825

Email address

akhondi@ssu.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-12-30, 1400/10/09

Expected recruitment end date

2022-12-30, 1401/10/09

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of the Effectiveness of Direct-Acting Antiviral

(DAA) Regimens in Patients with Hepatitis C: A Multicenter and Follow-up Analysis

Public title

Evaluation of Direct-Acting Antiviral (DAA) Regimens on hepatitis C.

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Adults (≥ 18 years) regardless of their previous treatment or stage of liver fibrosis

Exclusion criteria:

The patients who took drugs including carbamazepine, phenytoin, rifampin, phenobarbital, antacids and rosuvastatin had a history of taking amiodarone in the past three months those with severe renal insufficiency pregnant women patients with no high life expectancy due to other diseases

Age

From **18 years** old

Gender

Both

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **51**

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

Ethics committee of Yazd Shahid Sadoughi University of Medical Sciences

Street address

School of Medicine, Shahid Sadoughi University of Medical Sciences, Shohaday-e- Gomnam Blvd., Alem Sq., Yazd, Iran

City

Yazd

Province

Yazd

Postal code

8915173143

Approval date

2019-01-27, 1397/11/07

Ethics committee reference number

IR.SSU.MEDICINE.REC.1397.212

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 virological response

Timepoint

After 12 weeks

Method of measurement

Polymerase Chain Reaction (PCR)

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: In this study, therapeutic DAA regimen prescribed for the treatment of the patients with GT3 virus was SOF 400 mg + DCV 60 mg. For the other GT cases, it was SOF 400 mg + LDV 90. According to the recommended instructions, the drugs were taken on an outpatient basis every day. Twelve weeks after the completion of the DAA treatment, the RNA levels of serum HCV were analyzed separately in different GTs using PCR.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Yazd Shahid Sadoughi Hospital

Full name of responsible person

Mohsen Akhondi Meybodi

Street address

Shahid Sadoughi hospital, Ebne- Sina Ave., Yazd, Iran

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Yazd University of Medical Sciences
Full name of responsible person
Masoud Mirzaei
Street address
Bahonar Sq., Shahid Sadoughi Ave., Shahid Sadoughi
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Postal code
8916978477
Phone
+98 35 3146 2136
Email
mmirzaei@ssu.ac.ir
Grant name
Grant code / Reference number
**Is the source of funding the same sponsor
organization/entity?**
Yes
Title of funding source
Yazd University of Medical Sciences
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
Yazd University of Medical Sciences
Full name of responsible person
Mohsen Akhondi Meybodi
Position
Assistant Professor

Latest degree
Specialist
Other areas of specialty/work
Infectious diseases
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Person responsible for updating data

Contact

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Sharing plan**Deidentified Individual Participant Data Set (IPD)**

Undecided - It is not yet known if there will be a plan to make this available

Study Protocol

Undecided - It is not yet known if there will be a plan to

make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available