Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 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
City

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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 University of Medical Sciences, Yazd
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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

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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