Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Jun 2026

Efficacy of Daclatasvir and Sofosbuvir (Sovodak) with Ribavirin and without Ribavirin in cirrhosis and non cirrhosis patients with HCV in Gastrointestinal and Liver Disease Research Center in 2017

Protocol summary

Study aim

1-Assessment of efficacy of Daclatasvir and Sofosbuvir (Sovodak) without Ribavirin in non cirrhosis patients 2-Assessment of efficacy of Daclatasvir and Sofosbuvir (Sovodak) with Ribavirin in cirrhosis patients

Design

16 people with hepatitis C who are from Guilan cohort studies and have entry conditions into this program will be studied. This study is the third phase of a clinical trial without blinding. The patients HCV would slightly confirm with PCR. Then cirrhosis would diagnose by fibroscan, or clinical symptoms of cirrhosis such as ascits and splenomegaly.

Settings and conduct

This study will be carried out in Gastrointestinal and Liver disease research center. Non-cirrhosis patients will be treated with 400 mg sofosbovir and 60 mg Daclatasvir (Sovodak) one daily dose by Abidi for 12 weeks. Duration of treatment in patients with cirrhosis will be about 12 weeks. Cirrhosis patients will be treated with 400 mg sofosbovir and 60 mg Daclatasvir (Sovodak) and 1000 mg ribavirin/day if the patients have less than 75 kg or 1200 mg/day if they have 75 kg or more. The necessary tests will be done in 0,2,4,8,12 and 24 (12weeks after the ends od treatment) by HCV RNA.

Participants/Inclusion and exclusion criteria

Patients who have not been treated before Patients who had been treated before, but their illness recurred Patients who could not take interferon condition of failure: Patients who did not use the medication completely Patients with severe drug side effects Patients who were reluctant to participate in the plan

Intervention groups

This study has 2 group. Each 2 groups will be treated with 400 mg sofosbovir and 60 mg Daclatasvir (Sovodak). The first group includes patients with no cirrhosis and only receive Sovodak for 12 weeks and will be considered as a control group. The second group includes patients with cirrhosis and in addition to consumption Sovodak for 12 weeks, Ribavirin will also be added to their medication and will be considered as a intervention group regimen.

Main outcome variables

The main consequences of this study is the treatment of patients with hepatitis C in Guilan cohort.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20080901001155N30**
Registration date: **2018-10-24, 1397/08/02**
Registration timing: **retrospective**

Last update: **2018-10-24, 1397/08/02**
Update count: **0**

Registration date

2018-10-24, 1397/08/02

Registrant information

Name

Farahnaz Joukar

Name of organization / entity

Guilan University of Medical Sciences, Gastrointestinal and liver disease Research Center

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Gastrointestinal and Liver Disease Research Center-Guilan University of Medical Sciences

Expected recruitment start date
2017-11-04, 1396/08/13
Expected recruitment end date
2018-01-03, 1396/10/13
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Efficacy of Daclatasvir and Sofosbuvir (Sovodak) with Ribavirin and without Ribavirin in cirrhosis and non cirrhosis patients with HCV in Gastrointestinal and Liver Disease Research Center in 2017

Public title
Efficacy of Daclatasvir and Sofosbuvir (Sovodak) in patients with HCV
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Patients who have not been treated before Patients who had been treated before, but their illness recurred Patients who could not take interferon
Exclusion criteria:
Patients who did not use the medication completely Patients with severe drug side effects Patients who were reluctant to participate in the plan
Age
From **35 years** old to **75 years** old
Gender
Both

Phase
3
Groups that have been masked
No information
Sample size
Target sample size: **16**
Randomization (investigator's opinion)
N/A
Randomization description
Blinding (investigator's opinion)
Not blinded
Blinding description
Placebo
Not used
Assignment
Parallel
Other design features
No comments

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Committee of Guilan University of Medical Sciences.
Street address
Research and Technology Deputy ,Shaheed Beheshti street,Gaz square
City
Rasht
Province
Guilan
Postal code
41448956655
Approval date
2017-10-07, 1396/07/15
Ethics committee reference number
IR.GUMS.REC.1396.249

Health conditions studied

1

Description of health condition studied
Hepatitis C
ICD-10 code
A00-B99
ICD-10 code description
Chapter I Certain infectious and parasitic diseases,Viral hepatitis (B15-B19)

Primary outcomes

1

Description
HCV treatment
Timepoint
12 weeks after the end of treatment
Method of measurement
HCV- RNA PCR

Secondary outcomes

1

Description
possible side effect
Timepoint
Weeks 0.2, 4, 8, 12 and response to treatment, 24 weeks after the end of drug use (SVR 24
Method of measurement
weeks 2, 12 and 24 weeks after the end of drug use with use of PCR and 4,8 with use of liver enzymes test

Intervention groups

1

Description
Intervention group: 1.intervention group is cirrhosis patients with hepatitis C that would take 12 weeks of Sofosbovir 400 mg and Daclatasvir 60 mg (Sovodak) 1 pill made by Abidi plus Ribavirin/day 1000 mg if the patients have less than 75 kg or 1200 mg/day if they have 75 kg or more (5 or 6 × 200 mg tablets in a divided daily dose) made by Bakhtar bioshimi.

Category
Treatment - Drugs

2

Description
Control group: 2. Control group is non-cirrhosis patients with hepatitis C that would take 12 weeks of Sofosbovir 400 mg and Daclatasvir 60 mg (Sovodak) 1 pill made by Abid

Category
Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
Gastrointestinal and Liver Diseases Research Center

Full name of responsible person
Dr Farahnaz Jokar

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Gastrointestinal and Liver Diseases Research Center, Razi Hospital, Sardare Jangal Avenue

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Rasht University of Medical Sciences

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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
Rasht 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
Rasht University of Medical Sciences

Full name of responsible person
Dr. Farahnaz Joukar

Position
Deputy of Gastrointestinal and Liver Diseases Research Center

Latest degree
Ph.D.

Other areas of specialty/work
Epidemiology

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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
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
Title and more details about the data/document
The main outcome of this study is the hepatitis C treatment in Guilan cohort study , which will be available to the general public.
When the data will become available and for how long
A year after printing results
To whom data/document is available
Researchers at relevant research centers, universities, and related doctors
Under which criteria data/document could be used
In this case, the decision has not yet been taken
From where data/document is obtainable
Sara yeganeh Gastrointestinal and Liver Diseases Research Center, Razi hospital, Rasht 00981333535116 955655-41448 Yeganeh_sara6@yahoo.com
What processes are involved for a request to access data/document
At the outset, the applicant will email and complete his or her full introduction of the organization and the purpose of obtaining this data and will request the relevant documents or files.Subsequently, the data files will be made available to the applicant within the time period stated by the relevant investigator.
Comments