

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 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)

Phone

+98 13 1553 5116

Email address

info@glrc.org

Recruitment status

Recruitment complete

Funding source

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

Street address

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

City

Rasht

Province

Guilan

Postal code

41448956655

Phone

+98 13 3351 9248

Fax

+98 13 3353 4951

Email

farajov@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Rasht University of Medical Sciences

Full name of responsible person

Dr.Mir Saeed Attarchi

Street address

Sadati st, Namjoo st

City

Rasht

Province

Guilan

Postal code

4144666949

Phone

+98 13 3336 2772

Email

msattarchi@yahoo.com

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

Street address

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

City

Rasht

Province

Guilan

Postal code

41448956655

Phone

+98 13 3353 5116

Fax

Email

farajov@yahoo.com

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity

Rasht University of Medical Sciences

Full name of responsible person

Dr.Fariborz Mansour-Ghanaei

Position

Full Professor of Internal Medicine & Gastroenterology

Latest degree

Subspecialist

Other areas of specialty/work**Street address**

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

City

Rasht

Province

Guilan

Postal code

41448956655

Phone

+98 13 3353 5116

Fax**Email**

ghanaie@yahoo.com

Web page address**Fax****Email**

Yeganeh_sara6@yahoo.com

Web page address**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**Person responsible for updating data****Contact****Name of organization / entity**

Rasht University of Medical Sciences

Full name of responsible person

Sara Yeganeh

Position

Master of Microbiology

Latest degree

Master

Other areas of specialty/work

Microbiology

Street address

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

City

Rasht

Province

Guilan

Postal code

41448956655

Phone

+98 13 3353 5116