Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 2026

Efficacy and safety of Sobiovir(Sofosbuvir) and Daklibiox (Daclatasvir) for treatment of Hepatitis C in patient with thalassemia

Protocol summary

Summary

In this study, thalassemia patients with hepatitis C have entered. These people have hepatitis C who have failed previous treatment have been cured. Patients with cirrhosis(the result of fibroscan) or not treated for 3 months (non-cirrhotic) and 6 months (in cirrhotic) The drug used in this study, Svbvsfvvyr (60 mg) once a day and Daklatasvyr (400 mg) once a day.During the study each month to tolerate treatment and side effects, patient follow-up will be. After completion of the treatment based on the result of counting the number of virus by PCR response to treatment is determined

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2017052426097N2**
Registration date: **2017-06-24, 1396/04/03**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2017-06-24, 1396/04/03

Registrant information

Name
Jamshid Vafaeemanesh
Name of organization / entity
Qom University of Medical Sciences
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Iran (Islamic Republic of)
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+98 252931933
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j.vafaeemanesh@muq.ac.ir

Recruitment status

Recruitment complete

Funding source

Research Deputy of Iran University of Medical Sciences

Expected recruitment start date

2016-12-21, 1395/10/01

Expected recruitment end date

2017-05-22, 1396/03/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Efficacy and safety of Sobiovir(Sofosbuvir) and Daklibiox (Daclatasvir) for treatment of Hepatitis C in patient with thalassemia

Public title

Effective treatment and sobaiovir and daclatasvir in treatment of Hepatitis C

Purpose

Treatment

Inclusion/Exclusion criteria

Persons with thalassemia major, which has a history of hepatitis C are and once in the past but failed treatment with interferon treatment were enrolled if they consent

Age

No age limit

Gender

Both

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: **100**

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
Iran university of medical sciences
Street address
Tehran - Hemmat - next to Milad Hospital
City
tehran
Postal code
Approval date
2017-04-24, 1396/02/04
Ethics committee reference number
IR.IUMS.REC1396.30169

Health conditions studied

1

Description of health condition studied
Chronic viral hepatitis C
ICD-10 code
B18.2
ICD-10 code description
Chronic viral hepatitis C

Primary outcomes

1

Description
The number of hepatitis C virus
Timepoint
18/5000 After treatment
Method of measurement
The number of virus by PCR

Secondary outcomes

1

Description
Complications of Treatment
Timepoint
Questionnaires and blood tests
Method of measurement
Blood samples and questionnaires of Complications , per month

Intervention groups

1

Description
Antiretroviral therapy in all patients with Daclatacvirr and sobaiovir - before and after treatment
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Gastroenterology Research Center of Iran University of Medical Sciences
Full name of responsible person
vafaeimanesh jamshid
Street address
City
firozgar hospital

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Research Deputy of Iran University of Medical Sciences
Full name of responsible person
moosavi, alijavad,MD
Street address
Hemmat. Next to Milad Hospital. Iran University
City
tehran
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Research Deputy of Iran University of Medical Sciences
Proportion provided by this source
100
Public or private sector
empty
Domestic or foreign origin
empty
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
empty

Person responsible for general inquiries

Contact

Name of organization / entity
Iran university of medical silences

Full name of responsible person
vafaeimanesh jamshid

Position
Fellowship of Gastroenterology and Hepatology

Other areas of specialty/work

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Firoozgar Hospital - Vali Asr Square - Division of Gastroenterology

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Person responsible for scientific inquiries

Contact

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Qom university of medical siences

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associate profesor

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iran university of medical silences

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vafaeimanesh jamshid ,MD

Position
felloship of Gastroenterology and Hepatology

Other areas of specialty/work

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00

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Web page address

Sharing plan

Deidentified Individual Participant Data Set (IPD)
empty

Study Protocol
empty

Statistical Analysis Plan
empty

Informed Consent Form
empty

Clinical Study Report
empty

Analytic Code
empty

Data Dictionary
empty