

Clinical Trial Protocol

Iranian Registry of Clinical Trials

09 Jun 2026

Efficacy and safety of Sobiobir(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, Svbvsvvyr (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 Vafaemanesh

Name of organization / entity

Qom University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 252931933

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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 Sobiobir(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 Daclatacivir 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

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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 sciences

Full name of responsible person

vafaemanesh jamshid

Position

Fellowship of Gastroenterology and Hepatology

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

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Person responsible for updating data

Contact

Name of organization / entity

iran university of medical sciences

Full name of responsible person

vafaemanesh jamshid ,MD

Position

felloship of Gastroenterology and Hepatology

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Qom university of medical sciences

Full name of responsible person

vafaemanesh jamshid

Position

associate profesor

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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