

# 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, 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 Vafaemanesh

##### Name of organization / entity

Qom University of Medical Sciences

##### Country

Iran (Islamic Republic of)

##### Phone

+98 252931933

##### Email address

j.vafaemanesh@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 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

##### 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 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

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**Other areas of specialty/work****Street address****City****Postal code****Phone**

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

## 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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**City**

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**Postal code**

3716615476

## 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*