Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

Molecular investigation of hepatitis c virus before and after direct acting antiviral (DAA) therapy in thalasemia patients

Protocol summary

Study aim
Identification of drug resistence related mutations
Design
In this study 100 patients that met the inclusion criteria included thalassemia patients have history of chronic HCV (all genotypes) refered to Firoozgar Hospital; each participant specified a registry code.
Settings and conduct
Firoozgar Hospital and Gastrointestinal and Liver Diseases Research Center, Iran University,Tehran.
Participants/Inclusion and exclusion criteria
Thalassemia major patient that have chronic HCV infection, more than 18 years old, HCV/HBV co-infection, HCC or compensated cirrhosis without any limitation were included.
Intervention groups
Daclatasvir (60mg) plus Sofosbovir (400mg) per day 12W in non cirrhotic and 24W in compensated cirrhotic patient.
Main outcome variables
HCV Viral Load

General information

Reason for update
Acronym
TH-hepC-FS
IRCT registration information
IRCT registration number: **IRCT20171125037624N2**
Registration date: **2018-01-26, 1396/11/06**
Registration timing: **registered_while_recruiting**

Last update: **2018-01-26, 1396/11/06**
Update count: **0**
Registration date
2018-01-26, 1396/11/06

Registrant information

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Recruitment status
Recruitment complete
Funding source

Expected recruitment start date
2017-04-21, 1396/02/01
Expected recruitment end date
2019-02-20, 1397/12/01
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Molecular investigation of hepatitis c virus before and after direct acting antiviral (DAA) therapy in thalasemia patients

Public title
Molecular investigation of hepatitis c virus before and after drug therapy
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Thalassemia major patient that have chronic HCV infection more than 18 years old, HCV/HBV co-infection, HCC or compensated cirrhosis without any limitation were included.
Exclusion criteria:

Patients that have HIV/HCV co-infection and pregnant women were excluded.

Age

From **18 years** old

Gender

Both

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: **100**

More than 1 sample in each individual

Number of samples in each individual: **2**

befor and after drug therapy

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

Ethics committee of Iran University of Medical Sciences

Street address

Hemat Highway next to Milad Tower, Tehran, Iran University of Medical Sciences

City

Tehran

Province

Tehran

Postal code

1449614535

Approval date

2017-04-09, 1396/01/20

Ethics committee reference number

IR.IUMS.REC1396.30299

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

Viral Load

Timepoint

before and at the end of treatment

Method of measurement

quantitative evaluation viral particles

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Antiviral treatment with Sofosbuvir and Daclatasvir in all patients, Molecular survey on HCV before and after treatment.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Firoozgar Hospital and Gastrointestinal and Liver Diseases Research Center,

Full name of responsible person

Fahimeh Safarnezhad Tameshkel

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Sponsors / Funding sources

1

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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
Iran 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
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be a plan to make this available

Study Protocol
Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan
Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be 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