

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

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

Protocol summary

Study aim

Identification of drug resistance related mutations

Design

In this study 100 patients that met the inclusion criteria included thalassemia patients have history of chronic HCV (all genotypes) referred 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 Sofosbuvir (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

Name

Hossein Keyvani

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 8871 5350

Email address

keyvani.h@iums.ac.ir

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 thalassemia 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**

before 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

Street address

Beh Afarin Street, Vali Asr Square, Firoozgar Hospital

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1593748711

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Fahime.1615@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Iran University of Medical Sciences

Full name of responsible person

Seyed Kazem Malakouti

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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**

Iran University of Medical Sciences

Full name of responsible person

Mohammad hadi karbalaie niya

Position

researcher

Latest degree

Ph.D.

Other areas of specialty/work

Virology

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Person responsible for scientific inquiries**Contact****Name of organization / entity**

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Hossein Keyvani

Position

professor

Latest degree

Ph.D.

Other areas of specialty/work

Virology

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

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Full name of responsible person

Fahimeh Safarnezhad Tameshkel

Position

Researcher

Latest degree

Master

Other areas of specialty/work

Medical Genetics

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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