Clinical Trial Protocol
Iranian Registry of Clinical Trials

01 Jul 2026

Safety study of Sofosbuvir 800mg and Daclatasvir 120mg in adult outpatients with COVID-19

Protocol summary

Study aim
Evaluating the safety of sofosbuvir 800mg /Daclatasvir 120 mg in outpatient with COVID 19
Design
Study group: one arm open-label study with only one intervention group consists of 50 patients followed for 10 days
Settings and conduct
Patients will be recruited from the outpatient's clinic of Shariati hospital. Eligible patients will be included in the study and will receive orally the tablet of Daclatasvir 60 mg/sofosbuvir 400 mg twice per day (total of Daclatasvir 120 mg/sofosbuvir 800 mg)
Participants/Inclusion and exclusion criteria
Participants: Both sexes age higher than 18 years old Inclusion criteria: Diagnosis of COVID 19 Patients that do not need to be admitted in hospital Exclusion criteria: Patients without consent form, Patients that can not come for follow-up, Pregnancy or breastfeeding, Renal insufficiency with eGFR less than 30, or serum creatinin higher than 2.5 mg/dl in male and 2 mg/dl in female or need dialysis, Heart rate less than 50/ min, Hepatitis B infection, Amiodarone and or Warfarin consumption
Intervention groups
Intervention group: sofosbuvir 800 mg/Daclatasvir 120 mg: combined tablet Sofosbuvir 400/daclatasvir 60 twice daily (Sovodak, Fanavaran Rojan Mohaghegh Daru Co., Tehran, Iran) for 10 days.
Main outcome variables
Any related or non related adverse events occurred during study period

General information

Reason for update
Acronym
IRCT registration information
IRCT registration number: **IRCT20200128046294N3**
Registration date: **2020-10-22, 1399/08/01**
Registration timing: **prospective**

Last update: **2020-10-22, 1399/08/01**
Update count: **0**
Registration date
2020-10-22, 1399/08/01

Registrant information
Name
Anahita Sadeghi
Name of organization / entity
Country
Iran (Islamic Republic of)
Phone
+98 21 8241 5104
Email address
a-sadeghi@tums.ac.ir

Recruitment status
Recruitment complete
Funding source

Expected recruitment start date
2020-10-24, 1399/08/03
Expected recruitment end date
2020-12-20, 1399/09/30
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Safety study of Sofosbuvir 800mg and Daclatasvir 120mg in adult outpatients with COVID-19

Public title
Safety of Sofosbuvir /Daclatasvir in outpatients with COVID-19
Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Both sexes Age higher than 18 years old Diagnosis of COVID 19 Patients that do not need to be admitted in hospital

Exclusion criteria:

Patients without consent form Patients that can not come for follow-up Pregnancy , breast feeding Renal insufficiency with eGFR less than 30 , or serum creatinin higher than 2.5 mg/dl in male and 2 mg/dl in female Heart rate less than 50/ min Hepatitis B infection Amiodarone and /or Warfarin consumption

Age

From **18 years** old

Gender

Both

Phase

1-2

Groups that have been masked

No information

Sample size

Target sample size: **50**

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 Digestive Disease Research Institute - Tehran University of Medical Sciences

Street address

Digestive Disease Research Institute, Shariati Hospital, Kargar Street, Tehran

City

Tehran

Province

Tehran

Postal code

1411713135

Approval date

2020-10-13, 1399/07/22

Ethics committee reference number

IR.TUMS.DDRI.REC.1399.024

Health conditions studied

1

Description of health condition studied

COVID-19

ICD-10 code

U07.2

ICD-10 code description

Clinical or epidemiological diagnosis of COVID-19 where laboratory confirmation is inconclusive or not available.

Primary outcomes

1

Description

Related or non -related adverse events

Timepoint

Before intervention and 48 hours after the end of the study (day 12 of study)

Method of measurement

Daily follow-up

Secondary outcomes

1

Description

Time to clinical recovery

Timepoint

Before intervention and 48 hours after the end of the study (day 12 of study)

Method of measurement

Clinical Follow-up

2

Description

Hospitalization

Timepoint

Before intervention and 48 hours after the end of the study (day 12 of study)

Method of measurement

Clinical follow-up

3

Description

Death

Timepoint

Before intervention and 48 hours after the end of the study (day 12 of study)

Method of measurement

Clinical follow-up

Intervention groups

1

Description

Intervention group: receiving Sofosbuvir 800mg and

Daclatasvir 120mg (two drugs combination of Sofosbuvir 400mg and Daclatasvir 60mg, two tablets per day, Sovodak) produced by :Fanavaran Rojan Mohaghegh Daru Co., Tehran, Iran. for 10 days

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Shariati hospital

Full name of responsible person

Neda Alijani

Street address

Shariati Hospital, North Kargar Street

City

Tehran

Province

Tehran

Postal code

1411713135

Phone

+98 21 8490 1000

Email

dna1461@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Shahin Merat

Street address

Shariati hospital, North Kargar Street, Tehran

City

Tehran

Province

Tehran

Postal code

1411713135

Phone

+98 21 8241 5000

Email

shahin.merat@gmail.com

Grant name

ITPC-2020

Grant code / Reference number

ITPC-2020

Is the source of funding the same sponsor organization/entity?

No

Title of funding source

International Treatment Preparedness Coalition

Proportion provided by this source

100

Public or private sector

Public

Domestic or foreign origin

Foreign

Category of foreign source of funding

UN agencies and international organizations

Country of origin

Type of organization providing the funding

Academic

Person responsible for general inquiries

Contact

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Anahita Sadeghi

Position

Assistant Professor

Latest degree

Subspecialist

Other areas of specialty/work

Internal Medicine

Street address

Shariati hospital, North Kargar Street, Tehran

City

Tehran

Province

Tehran

Postal code

1411713135

Phone

+98 21 8241 5176

Email

anahita825@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Anahita Sadeghi

Position

Assistant Professor

Latest degree

Subspecialist

Other areas of specialty/work

Internal Medicine

Street address

Shariati hospital, North Kargar Street, Tehran

City

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Tehran

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1411713135

Phone

+98 21 8241 5176

Email

anahita825@gmail.com

Person responsible for updating data

Contact

Name of organization / entity
Tehran University of Medical Sciences

Full name of responsible person
Anahita Sadeghi

Position
Assistant Professor

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1411713135

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anahita825@gmail.com

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