

Clinical Trial Protocol

Iranian Registry of Clinical Trials

09 Jun 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

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1411713135

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dna1461@yahoo.com

Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Tehran University of Medical Sciences

Full name of responsible person

Shahin Merat

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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

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

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Full name of responsible person

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Position

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Latest degree

Subspecialist

Other areas of specialty/work

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Person responsible for updating data

Contact

Name of organization / entity

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Full name of responsible person

Anahita Sadeghi

Position

Assistant Professor

Latest degree

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Other areas of specialty/work

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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