

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

30 Oct 2020

### Evaluation of the effect of sofosbuvir/daclatasvir in COVID-19 patients: a double-blind randomized clinical trial

#### Protocol summary

##### Study aim

Determination of the effect of sofosbuvir/daclatasvir in COVID-19 patients

##### Design

A clinical trial with a, with parallel control group, double-blind, randomized, phase 3, and multicenter groups per 1000 patients.

##### Settings and conduct

The study is a double-blind clinical trial. The sample size is 1000. The patients are selected according to the eligibility criteria and are assigned to the intervention and control groups by a simple random method. participants, researchers, Care providers, Data analyzers, and outcome assessors are blind. The drugs used were similar in appearance.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: Age:  $\geq 18$ , One of the following signs: Fever  $\geq 37.8^{\circ}\text{C}$  at any one time, Dry cough, Severe fatigue, Dyspnea, CT appearance compatible with COVID, O2Sat 94% or less Exclusion criteria: Renal failure (eGFR  $< 30$ ) Bradycardia (HR  $< 50$ ), Taking amiodarone, Previous sofosbuvir use, Pregnancy/lactation, Multi-organ failure on admission (2 organs or more, excluding lung), Requiring intubation on admission, Significant arrhythmia in EKG, Allergy to sofosbuvir or daclatasvir, not consenting to the study

##### Intervention groups

Intervention group: Country Standard Pharmaceutical Protocol + SOF/DCV (400mg/60mg) one tablet daily for 10 days. Control group: Country Standard Pharmaceutical Protocol + placebo one tablet daily for 10 days.

##### Main outcome variables

Recovery within 10 days since the start of taking medicine. Recovery defined as: (No fever, No dyspnea, No or improved cough, No or improved fatigue, PO tolerance) for 24 hours

#### General information

##### Reason for update

Edit the sponsorship section

##### Acronym

DISCOVER

##### IRCT registration information

IRCT registration number: **IRCT20200624047908N1**

Registration date: **2020-07-05, 1399/04/15**

Registration timing: **prospective**

Last update: **2020-10-04, 1399/07/13**

Update count: **5**

##### Registration date

2020-07-05, 1399/04/15

##### Registrant information

###### Name

gholamali eslami

###### Name of organization / entity

###### Country

Iran (Islamic Republic of)

###### Phone

+98 61 5326 5363

###### Email address

gholamali.eslami1351@gmail.com

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2020-07-13, 1399/04/23

##### Expected recruitment end date

2020-09-08, 1399/06/18

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

## Scientific title

Evaluation of the effect of sofosbuvir/daclatasvir in COVID-19 patients: a double-blind randomized clinical trial

## Public title

Evaluation of the effect of sofosbuvir/daclatasvir in COVID-19 patients

## Purpose

Treatment

## Inclusion/Exclusion criteria

### Inclusion criteria:

Age  $\geq 18$  One of the following signs: Fever  $\geq 37.8^{\circ}\text{C}$  at any one time, Dry cough, Severe fatigue, Dyspnea CT appearance compatible with COVID O2 Saturation 94% or less

### Exclusion criteria:

Renal failure (eGFR  $< 30$ ) Bradycardia (HR  $< 50$ ) Taking amiodarone Previous sofosbuvir use Pregnancy/lactation Multi-organ failure on admission (2 organs or more, excluding lung) Requiring intubation on admission Significant arrhythmia in EKG Allergy to sofosbuvir or daclatasvir Not consenting to the study

## Age

From **18 years** old

## Gender

Both

## Phase

3

## Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser

## Sample size

Target sample size: **1000**

## Randomization (investigator's opinion)

Randomized

## Randomization description

This study will be a randomized, double-blind, phase 3, and multicenter clinical trials on 1000 patients. The randomization method is block randomization and the block size is 4. Sealed envelopes are used for the allocation concealment.

## Blinding (investigator's opinion)

Double blinded

## Blinding description

In this study participants, researchers, Care providers, Data analyzers, and outcome assessors are blind. The medicine and placebo are similar in appearance, so patients do not understand which group they are in.

## Placebo

Used

## Assignment

Parallel

## Other design features

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Abadan School of Medical Sciences

##### Street address

Abadan School of Medical Sciences

##### City

Abadan

##### Province

Khuzestan

##### Postal code

6313833177

#### Approval date

2020-06-21, 1399/04/01

#### Ethics committee reference number

IR.ABADANUMS.REC.1399.071

## Health conditions studied

### 1

#### Description of health condition studied

COVID-19

#### ICD-10 code

COVID-19

#### ICD-10 code description

U07.1

## Primary outcomes

### 1

#### Description

Recovery within 10 days of starting the drug. Recovery means: (no fever, no shortness of breath, no cough or improved, no fatigue or improved, tolerated oral nutrition) for 24 hours.

#### Timepoint

Daily

#### Method of measurement

Clinical observation and examination

## Secondary outcomes

### 1

#### Description

Recovery within 14 days from start of medication

#### Timepoint

Daily

#### Method of measurement

Clinical observation and examination

### 2

#### Description

Rate of survival

#### Timepoint

Daily

**Method of measurement**

census report

**3**

**Description**

Days admitted in hospital

**Timepoint**

Daily since hospitalization time

**Method of measurement**

Based on patient's file

**4**

**Description**

Days intubated/under ventilator

**Timepoint**

Daily

**Method of measurement**

observation

**5**

**Description**

Days admitted in ICU

**Timepoint**

Daily

**Method of measurement**

Based on patient's file

**Intervention groups**

**1**

**Description**

Intervention group: Country Standard Pharmaceutical Protocol + SOF/DCV (400mg/60mg) one tablet daily for 10 days

**Category**

Treatment - Drugs

**2**

**Description**

Control group: Country Standard Pharmaceutical Protocol + placebo one tablet daily for 10 days.

**Category**

Placebo

**Recruitment centers**

**1**

**Recruitment center**

**Name of recruitment center**

Abadan,Ayatollah Taleghani Hospital

**Full name of responsible person**

Gholamali Eslami

**Street address**

Ayatollah Taleghani Hospital , Station 12, in front of Azad University , Abadan, Khuzestan, Iran

**City**

Abadan

**Province**

Khuzestan

**Postal code**

-

**Phone**

+98 61 5336 1003

**Email**

gholamali.eslami1351@gmail.com

**2**

**Recruitment center**

**Name of recruitment center**

Abadan Oil Industry Imam Khomeini Hospital

**Full name of responsible person**

Gholamali Eslami

**Street address**

NO.671, Imam Khomeini Hospital, cyclin next to the refinery of Montazeri St, Abadan city, Khuzestan, IRAN

**City**

Abadan

**Province**

Khuzestan

**Postal code**

-

**Phone**

+98 61 5322 6811

**Email**

gholamali.eslami1351@gmail.com

**3**

**Recruitment center**

**Name of recruitment center**

Zabol

**Full name of responsible person**

Mehdi Afshari

**Street address**

Rajae street, University of Medical Sciences

**City**

Zabol

**Province**

Sistan-va-Balouchestan

**Postal code**

9861615881

**Phone**

+98 54 3223 2176

**Email**

mahdiafshari99@gmail.com

**4**

**Recruitment center**

**Name of recruitment center**

Tehran

**Full name of responsible person**

Anahita Sadeghi

**Street address**

kargar st,Tehran University of Medical Sciences Shariati hospital

**City**

Tehran  
**Province**  
Tehran  
**Postal code**  
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**Phone**  
+98 21 8241 5300  
**Fax**  
**Email**  
anahita825@gmail.com

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### Recruitment center

**Name of recruitment center**  
Ghom  
**Full name of responsible person**  
Ahmad Hormaty  
**Street address**  
Iavasany st, Ghom University of Medical Sciences  
**City**  
Ghom  
**Province**  
Ghoum  
**Postal code**  
3713649373  
**Phone**  
+98 25 3612 2053  
**Fax**  
**Email**  
hormatia@yahoo.com

## 6

### Recruitment center

**Name of recruitment center**  
Mazandaran  
**Full name of responsible person**  
Hamide Abaspor kasgary  
**Street address**  
Faculty of Pharmacy, Complex of the Great Prophet,  
Farahabad Road  
**City**  
Sary  
**Province**  
Mazandaran  
**Postal code**  
-  
**Phone**  
+98 11 3304 4000  
**Email**  
Dr.abbaspour1@yahoo.com

## Sponsors / Funding sources

## 1

### Sponsor

**Name of organization / entity**  
Abadan University of Medical Sciences  
**Full name of responsible person**  
Gholamali Eslami

### Street address

Deputy Minister of Educational Technology Research-  
Airport Square - Next to Ayatollah Jami International  
Airport , Abadan, Khuzestan, Iran

### City

Abadan

### Province

Khuzestan

### Postal code

6313833177

### Phone

+98 61 5326 5362

### Email

gholamali.eslami1351@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

Other

## Person responsible for general inquiries

### Contact

#### Name of organization / entity

Abadan University of Medical Sciences

#### Full name of responsible person

Gholamali Eslami

#### Position

Associate professor

#### Latest degree

Specialist

#### Other areas of specialty/work

Infectious diseases

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#### Email

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## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**

Abadan University of Medical Sciences

**Full name of responsible person**

Gholamali Eslami

**Position**

Associate professor

**Latest degree**

Specialist

**Other areas of specialty/work**

Infectious diseases

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## Person responsible for updating data

### Contact

**Name of organization / entity**

Abadan University of Medical Sciences

**Full name of responsible person**

Golamali Eslami

**Position**

Associate professor

**Latest degree**

Specialist

**Other areas of specialty/work**

Infectious diseases

**Street address**

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**City**

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**Province**

Khuzestan

**Postal code**

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006153265362

**Email**

golamali.eslami@gmail.com

## Sharing plan

**Deidentified Individual Participant Data Set (IPD)**

Yes - There is a plan to make this available

**Study Protocol**

Yes - There is a plan to make this available

**Statistical Analysis Plan**

Yes - There is a plan to make this available

**Informed Consent Form**

Yes - There is a plan to make this available

**Clinical Study Report**

Yes - There is a plan to make this available

**Analytic Code**

Yes - There is a plan to make this available

**Data Dictionary**

Yes - There is a plan to make this available

**Title and more details about the data/document**

All data can be shared after the participants in the study are unrecognizable.

**When the data will become available and for how long**

The data access period after publishing of the article

**To whom data/document is available**

The data in this study will be available for researchers working in academic and scientific institutions, as well as the Food and Drug Administration.

**Under which criteria data/document could be used**

Any analysis can be done by main researcher permission.

**From where data/document is obtainable**

gholamali.eslami1351@gmail.com

**What processes are involved for a request to access data/document**

The researcher or pharmaceutical company can send their request to the academic email of project manager. After ensuring the accuracy of the submitted documents, the project manager will provide the requested information to the researcher or pharmaceutical company in of one week.

**Comments**