

Clinical Trial Protocol

Iranian Registry of Clinical Trials

07 Aug 2022

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: ≥ 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 Recruitment centers

Acronym

DISCOVER

IRCT registration information

IRCT registration number: **IRCT20200624047908N1**

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

Registration timing: **prospective**

Last update: **2020-11-09, 1399/08/19**

Update count: **6**

Registration date

2020-07-05, 1399/04/15

Registrant information

Name

gholamali eslami

Name of organization / entity

Country

Iran (Islamic Republic of)

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+98 61 5326 5363

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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 ≥ 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

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Recruitment center

Name of recruitment center

Abadan Oil Industry Imam Khomeini Hospital

Full name of responsible person

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Recruitment center

Name of recruitment center

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Full name of responsible person

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Recruitment center

Name of recruitment center

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Recruitment center

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Full name of responsible person
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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

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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

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

Street address

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Person responsible for scientific inquiries

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Abadan University of Medical Sciences

Full name of responsible person

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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

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Position

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Latest degree

Specialist

Other areas of specialty/work

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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