Clinical Trial Protocol
Iranian Registry of Clinical Trials

05 Dec 2023

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 ≥ 37.8°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)
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 ≥18 One of the following signs: Fever ≥ 37.8°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
Khouzestan

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
Khouzestan
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
Khouzestan
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
Rajaee 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
1411713135

Phone
+98 21 8241 5300

Fax

Email
anahita825@gmail.com

5

Recruitment center

Name of recruitment center
Ghom

Full name of responsible person
Ahmad Hormaty

Street address
lavasany 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

7

Recruitment center

Name of recruitment center
Iranshahr

Full name of responsible person
Fateme Azarkish

Street address
Baluch St. Deputy of Research and Technology, Sistan and Baluchestan Province, Iranshahr

City
Iranshahr

Province
Sistan-va-Balouchestan

Postal code
۹۹۱۴۷۸۶۱۳۸

Phone
+98 54 3721 3328

Email
Azarkish2005@yahoo.com

8

Recruitment center

Name of recruitment center
Shiraz

Full name of responsible person
Zinab mehraby

Street address
Zand St., in front of Palestine St., the central building of Shiraz University of Medical Sciences, Shiraz

City
Shiraz

Province
Fars

Postal code
1433671348

Phone
+98 71 3230 5410

Email
mehrabizm4510@gmail.com

9

Recruitment center

Name of recruitment center
Bandar Abbas

Full name of responsible person
Elham Barahimi

Street address
Infectious and Tropical Diseases Research Center, Hormozgan Health Institute, Hormozgan University of Medical Sciences, Bandar Abbas, Iran

City
Bandar Abbas

Province
Hormozgan

Postal code
7916613885

Phone
+98 76 3371 0373

Email
dr.e.barahimi@gmail.com

10

Recruitment center

Name of recruitment center
Gheshm

Full name of responsible person
Mehdi Hassaniazad

Street address
Hormozgan University of Medical Sciences, Bandar

Abbas, Iran
City
Gheshm
Province
Hormozgan
Postal code
7916613885
Phone
+98 76 3371 0373
Email
Mehdihassaniazad@gmail.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
Khouzestan
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
Street address
Deputy Minister of Educational Technology Research- Airport Square - Next to Ayatollah Jami International Airport , Abadan, Khuzestan, Iran
City
Abadan
Province
Khouzestan
Postal code
6313833177
Phone
+98 61 5326 5362
Email
gholamali.eslami1351@gmail.com

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
Street address
Deputy Minister of Educational Technology Research- Airport Square - Next to Ayatollah Jami International Airport , Abadan, Khuzestan, Iran
City
Abadan
Province
Khouzestan
Postal code
6313833177
Phone
006153265362
Email
gholamali.eslami1351@gmail.com

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
Deputy Minister of Educational Technology Research- Airport Square - Next to Ayatollah Jami International Airport , Abadan, Khuzestan, Iran
City
Abadan
Province
Khouzestan
Postal code
6313833177
Phone
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