

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

24 Sep 2021

### Evaluation of the effects of Desferal on clinical symptoms in patients with COVID-19

#### Protocol summary

##### Study aim

Evaluation of the effects of Desferal on clinical symptoms in patients with COVID-19

##### Design

A phase 2-3 clinical trial with parallel group, open-label, 60 patients, block randomized method

##### Settings and conduct

This study will be conducted at the Shahid Mohammadi Hospital, Hormozgan University of Medical Sciences, Bandar Abbas. The study population is 60 patients with COVID-19 (30 patients in control group, and 30 in study group).

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: Age >18 years, positive polymerase chain reaction (PCR) test for COVID-19, primary clinical symptoms, hospitalized and moderate patients, and signing informed consent. criteria: Underlying diseases, including renal failure (serum creatinine >2), myocarditis and arrhythmia, anemia (hemoglobin <4-8), lower respiratory tract infection, and asthma, patients requiring intubation or frequent use of respiratory drugs, severe and critical patients, history of allergy to studied drug, and pregnancy and breastfeeding

##### Intervention groups

Group A will be patients receiving standard treatment of COVID-19 according to the Ministry of Health's protocol. Group B will be patients receiving, in addition to the standard treatment, Deferoxamine solution (500 mg) divided in four doses a day through a nebulizer for 7 days.

##### Main outcome variables

Checking the viral load, fever, O2 saturation, Evaluation of duration of hospitalization, C-reactive protein, Occurrence of adverse drug reactions

#### General information

##### Reason for update

##### Acronym

#### IRCT registration information

IRCT registration number: **IRCT20200506047323N4**

Registration date: **2020-08-01, 1399/05/11**

Registration timing: **prospective**

Last update: **2020-08-01, 1399/05/11**

Update count: **0**

#### Registration date

2020-08-01, 1399/05/11

#### Registrant information

##### Name

Mohammad Fathalipour

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 76 3371 0406

##### Email address

m.fathalipour@hums.ac.ir

#### Recruitment status

**Recruitment complete**

#### Funding source

#### Expected recruitment start date

2020-08-10, 1399/05/20

#### Expected recruitment end date

2020-10-10, 1399/07/19

#### Actual recruitment start date

empty

#### Actual recruitment end date

empty

#### Trial completion date

empty

#### Scientific title

Evaluation of the effects of Desferal on clinical symptoms in patients with COVID-19

#### Public title

Desferal in COVID-19

## Purpose

Treatment

## Inclusion/Exclusion criteria

### Inclusion criteria:

Age >18 years Positive polymerase chain reaction (PCR) test for COVID-19 Primary clinical symptoms Hospitalized and moderate patients Signing informed consent and willingness of study participant to accept randomization to any assigned treatment arm

### Exclusion criteria:

Underlying diseases, including renal failure (serum creatinine >2), myocarditis and arrhythmia, anemia (hemoglobin<4-8), lower respiratory tract infection, and asthma Patients requiring intubation or frequent use of respiratory drugs Severe and critical patients History of allergy to studied drug Pregnancy and breastfeeding

## Age

From **18 years** old

## Gender

Both

## Phase

2-3

## Groups that have been masked

*No information*

## Sample size

Target sample size: **60**

## Randomization (investigator's opinion)

Randomized

## Randomization description

Block randomization will be performed (each block consists 6 patients). Allocation sequence and concealment codes will be generated using [www.sealedenvelope.com](http://www.sealedenvelope.com). The closed envelope method will be used to hide the allocation sequence.

## Blinding (investigator's opinion)

Not blinded

## Blinding description

## Placebo

Not used

## Assignment

Parallel

## Other design features

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Ethics committee of Hormozgan University of Medical Sciences

##### Street address

Jomhuri Eslami Blvd

##### City

Bandar Abbas

##### Province

Hormozgan

## Postal code

7919915519

## Approval date

2020-07-25, 1399/05/04

## Ethics committee reference number

IR.HUMS.REC.1399.227

## Health conditions studied

### 1

#### Description of health condition studied

COVID-19, virus identified

#### ICD-10 code

U07.1

#### ICD-10 code description

COVID-19, virus identified

## Primary outcomes

### 1

#### Description

Viral load

#### Timepoint

Before intervention and 7 days after the start of the intervention

#### Method of measurement

Polymerase chain reaction (PCR) test

### 2

#### Description

Body temperature

#### Timepoint

Before intervention and daily during the study

#### Method of measurement

Thermometer

### 3

#### Description

Oxygen saturation

#### Timepoint

Before intervention and daily during the study

#### Method of measurement

Pulse oximeter

## Secondary outcomes

### 1

#### Description

Duration of hospitalization

#### Timepoint

Time period from admission to discharge

#### Method of measurement

Patient's file

### 2

#### Description

C-reactive protein  
**Timepoint**  
Before intervention and 7 days after the start of the intervention  
**Method of measurement**  
C-RP kit

### 3

**Description**  
Incidence of serious adverse events  
**Timepoint**  
Before intervention and daily during the study  
**Method of measurement**  
Questionnaire

## Intervention groups

### 1

**Description**  
Intervention group: The standard treatment regimen for COVID-19 along with a 10 cc (500 mg) of Deferoxamine solution (Deferoxir, Exirdaru Company, Iran) divided in four times a day through a nebulizer for a period of 7 days.  
**Category**  
Treatment - Drugs

### 2

**Description**  
Control group: The standard treatment for COVID-19 based on the Ministry of Health's protocol including hydroxychloroquine sulfate (Amin Pharmaceutical company, Isfahan) at a dose of 400 mg twice a day for the first day and 200 mg twice a day for 6 following days.  
**Category**  
Treatment - Drugs

## Recruitment centers

### 1

**Recruitment center**  
**Name of recruitment center**  
Shahid Mohammadi Hospital  
**Full name of responsible person**  
Parivash Davoodian  
**Street address**  
Jomhuri Eslami Blvd  
**City**  
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Hormozgan  
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**Email**

shmh@hums.ac.ir  
**Web page address**  
<http://shmh.hums.ac.ir/>

## Sponsors / Funding sources

### 1

**Sponsor**  
**Name of organization / entity**  
Bandare-abbas University of Medical Sciences  
**Full name of responsible person**  
Teamur Aghamolaei  
**Street address**  
Jomhuri Eslami Blvd  
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mail@hums.ac.ir  
**Web page address**  
<http://hums.ac.ir/>

**Grant name**  
**Grant code / Reference number**  
990204  
**Is the source of funding the same sponsor organization/entity?**  
Yes  
**Title of funding source**  
Bandare-abbas University of Medical Sciences  
**Proportion provided by this source**  
100  
**Public or private sector**  
Public  
**Domestic or foreign origin**  
Domestic  
**Category of foreign source of funding**  
empty  
**Country of origin**  
**Type of organization providing the funding**  
Academic

## Person responsible for general inquiries

**Contact**  
**Name of organization / entity**  
Bandare-abbas University of Medical Sciences  
**Full name of responsible person**  
Mohammad Fathalipour  
**Position**  
Assistant professor  
**Latest degree**  
Ph.D.  
**Other areas of specialty/work**  
Medical Pharmacy

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Emam Hossein Blvd  
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## Person responsible for scientific inquiries

### Contact

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**Position**  
Associate professor  
**Latest degree**  
Specialist  
**Other areas of specialty/work**  
Infectious diseases  
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parivash.davoodian@hums.ac.ir

## Person responsible for updating data

### Contact

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Assistant professor  
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**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

Undecided - It is not yet known if there will be a plan to make this available

### Clinical Study Report

Not applicable

### Analytic Code

Not applicable

### Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available

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

Information regarding the study outcomes will be shared

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

Data will become available after publication of obtained results

### To whom data/document is available

Only academic institutions

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

The study protocol or proposal should be approved by Ethics committee of institutions. The rights of authors and sponsors should be respected.

### From where data/document is obtainable

M.fathalipour@yahoo.com, and M.fathalipour@hums.ac.ir

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

Requests should be addressed to the Technology and Research Vice-chancellery of Hormozgan University of Medical Sciences and the project executor should be informed.

### Comments