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

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Iran (Islamic Republic of)

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+98 76 3371 0406

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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. 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

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Jomhuri Eslami Blvd

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Bandare-abbas University of Medical Sciences

Full name of responsible person

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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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Person responsible for scientific inquiries

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Person responsible for updating data

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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 informed.
Comments