Clinical Trial Protocol
Iranian Registry of Clinical Trials

28 Sep 2026

Evaluation of the efficacy of Hydroxyurea administration on blood oxygen saturation of hospitalized patients with severe COVID-19

Protocol summary

Study aim
Evaluation of the efficacy of Hydroxyurea administration on blood oxygen saturation of hospitalized COVID-19 patients

Design
Before-after clinical trial, single group, without randomization and blinding

Settings and conduct
This study will be performed on patients with severe COVID-19 hospitalized in Labafinejad patients (Tehran, Iran) in 2022. This study is performed on only one group of patients who all receive hydroxyurea tablets (500 mg three times a day) in addition to the usual COVID-19 treatments according to the national guideline. Peripheral blood oxygen saturation, hemoglobin F levels and blood cell counts are assessed every two days. Finally, the data are statistically analyzed.

Participants/Inclusion and exclusion criteria
Inclusion criteria are: Laboratory confirmation of Coronavirus disease-19 (COVID-19) virus by reverse transcription- polymerase chain reaction (RT-PCR); White blood cell count less than 2500 million cells per microliter; Absolute neutrophil count less than 1000 million cells per microliter; Platelet count less than 80,000 cells per microliter; more than 50% increase in creatinine compared to the amunts of admission time; Pregnancy; Active hepatitis B or C infections.

Intervention groups
This study is performed on only one group of patients who all receive hydroxyurea tablets (500 mg three times a day) in addition to the usual COVID-19 treatments according to the national guideline.

Main outcome variables
Peripheral blood oxygen saturation

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20210901052358N2**
Registration date: **2022-03-08, 1400/12/17**
Registration timing: **prospective**

Last update: **2022-03-08, 1400/12/17**
Update count: **0**

Registration date
2022-03-08, 1400/12/17

Registrant information

Name
Amirreza Keyvanfar

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 21 4483 1899

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amirrezakeyvanfar@sbmu.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2022-03-21, 1401/01/01

Expected recruitment end date
2022-04-21, 1401/02/01

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Evaluation of the efficacy of Hydroxyurea administration on blood oxygen saturation of hospitalized patients with severe COVID-19

Public title
Evaluation of the efficacy of Hydroxyurea administration on blood oxygen saturation of COVID-19 patients
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Laboratory confirmation of Coronavirus disease-19 (COVID-19) virus by reverse transcription- polymerase chain reaction (RT-PCR) Oxygen saturation less than 90% Respiratory rate more than 24 per minute More than 50% involvement of the lung parenchyma on CT scan
Exclusion criteria:
White blood cell count less than 2500 million cells per microliter Absolute neutrophil count less than 1000 million cells per microliter Platelet count less than 80,000 cells per microliter More than 50% increase in creatinine compared to the amounts of admission time Pregnancy Active hepatitis B or C infections
Age
From **18 years** old
Gender
Both

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **10**
Randomization (investigator's opinion)
N/A
Randomization description
Blinding (investigator's opinion)
Not blinded
Blinding description
Placebo
Not used
Assignment
Single
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Organizational Committee of Ethics in Biomedical Research, Shahid Beheshti University of Medical Sci
Street address
Shahid Beheshti University of medical sciences, Arabi St., Daneshjoo Blvd,. Yaman St,. Chamran highway.
City
Tehran
Province
Tehran
Postal code
1985717443
Approval date
2021-06-13, 1400/03/23
Ethics committee reference number
IR.SBMU.RETECH.REC.1400.135

Health conditions studied

1

Description of health condition studied
COVID-19
ICD-10 code
U07.1
ICD-10 code description
COVID-19, virus identified

Primary outcomes

1

Description
Peripheral blood oxygen saturation
Timepoint
Every other day after starting treatment (up to a week)
Method of measurement
Pulseoxymeter

2

Description
Hemoglobin F levels
Timepoint
Every other day after starting treatment (up to a week)
Method of measurement
Hemoglobin electrophoresis

3

Description
Blood cell count
Timepoint
Every other day after starting treatment (up to a week)
Method of measurement
Laboratory report

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: This study is performed on only one group of patients who all receive hydroxyurea tablets (500 mg three times a day) in addition to the usual COVID-19 treatments according to the national guideline. Usual treatments include serum therapy, vitamins, supplemental oxygen, and remdesivir (200 mg intravenously for first day and 100 mg daily intravenously for the next 4 days).

Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Labbafinejad hospital
Full name of responsible person
Amirreza Keyvanfar
Street address
9th Boostan St., Pasdaran, Tehran
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Shahid Beheshti University of Medical Sciences
Full name of responsible person
Dr. Afshin Zarghi
Street address
Shahid Beheshti University of Medical Sciences, No. 2, Arabi St., Yemen St., Chamran Highway, Tehran, Iran
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Mpajouhesh@sbmu.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Shahid Beheshti 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
Shahid Beheshti University of Medical Sciences
Full name of responsible person
Amirreza Keyvanfar
Position
Research assisstant
Latest degree
Medical doctor
Other areas of specialty/work
Infectious diseases
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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be a plan to make this available
Study Protocol
Undecided - It is not yet known if there will be a plan to make this available
Statistical Analysis Plan
Undecided - It is not yet known if there will be 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
Undecided - It is not yet known if there will be a plan to make this available
Analytic Code
Undecided - It is not yet known if there will be a plan to make this available
Data Dictionary
Undecided - It is not yet known if there will be a plan to make this available