

Clinical Trial Protocol

Iranian Registry of Clinical Trials

24 Jun 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 amounts 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

Email address

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

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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

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Shahid Beheshti University of Medical Sciences, No. 2, Arabi St., Yemen St., Chamran Highway, Tehran, Iran

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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 assistant

Latest degree

Medical doctor

Other areas of specialty/work

Infectious diseases

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Person responsible for scientific inquiries**Contact****Name of organization / entity**

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Full name of responsible person

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Position

Research assistant

Latest degree

Medical doctor

Other areas of specialty/work

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Person responsible for updating data**Contact**

Name of organization / entity

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Position

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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