

Clinical Trial Protocol

Iranian Registry of Clinical Trials

12 Jul 2026

Evaluating the efficacy and safety of remdesivir in severe COVID-19 in hospitalized patients

Protocol summary

Study aim

Evaluating the efficacy and safety of Remdesivir (Brand) in comparison to generic remdesivir

Design

Prospective double-blind clinical trial with parallel randomized groups using permuted block randomization method. This is a phase 3 clinical trial on 120 patients.

Settings and conduct

Place of study: Masih Daneshvari Hospital. How to do the study: 120 patients with COVID-19, using permuted block randomization will be divided in to two groups. The main investigator and the patients will be blind to the study groups.

Participants/Inclusion and exclusion criteria

Patients between 18 and 100 years old who have laboratory confirmed COVID-19 (Corona Virus Disease-19) with RT-PCR (Real-Time Polymerase Chain Reaction) and CT scan and are severally ill, will be included in the study. Furthermore, patients should have a $\text{SaO}_2/\text{SpO}_2 \leq 94\%$ on room air or a ratio of $\text{PaO}_2/\text{FiO}_2 < 300 \text{ mgHg}$, to be included in the study. The exclusion criteria are included pregnancy, breastfeeding, severe liver and renal disease, and drug interaction with remdesivir.

Intervention groups

120 patients are going to be divided in to two groups using permuted block randomization; each group will contain 60 patients. First group will receive remdesivir (Veklury) 200 mg for the first day then 100 mg for day 2 to 5. The second group will receive generic remdesivir (Ronak Daru) 200 mg for day one then 100 mg from day 2 to 5.

Main outcome variables

Time to clinical improvement

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20151227025726N28**

Registration date: **2021-10-21, 1400/07/29**

Registration timing: **registered_while_recruiting**

Last update: **2021-10-21, 1400/07/29**

Update count: **0**

Registration date

2021-10-21, 1400/07/29

Registrant information

Name

Farzaneh Dastan

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 912 270 5933

Email address

f_dastan@sbmu.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-09-21, 1400/06/30

Expected recruitment end date

2022-02-19, 1400/11/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluating the efficacy and safety of remdesivir in severe COVID-19 in hospitalized patients

Public title

Evaluating the effects of remdesivir in severe COVID-19 in hospitalized patients

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Patients above 18 years old Confirmed COVID-19 (Corona Virus Disease-19) with RT-PCR (Real-Time Polymerase Chain Reaction) Lung CT scan confirming lung involvement Hospitalized with SaO₂/SpO₂ ≤ 94% in room air or having PaO₂/FiO₂ < 300 mmHg Becoming symptomatic within the past two weeks

Exclusion criteria:

Severe liver disease (Child Pugh score ≥ C, AST > 10 times upper limit) Pregnancy Breastfeeding Severe renal failure (estimated glomerular filtration rate ≤ 30 mL/min/1.73 m²) or receiving dialysis Drug interactions (Methimazole, chloroquine, hydroxychloroquine)

Age

From **18 years** old to **100 years** old

Gender

Both

Phase

2-3

Groups that have been masked

- Participant
- Investigator

Sample size

Target sample size: **120**

Randomization (investigator's opinion)

Randomized

Randomization description

120 COVID-19 patients who are hospitalized in the COVID-19 ward of Masih Daneshvari Hospital will be randomized using permuted block randomization by Sealedenvelope.com site. The list of randomization containing 30 blocks each consisting 4 will be available for randomizer for assigning the drug and the control group. Following entering the study, cases will be randomized to study groups based on the list.

Blinding (investigator's opinion)

Double blinded

Blinding description

In this study, the main investigator and participants are unaware of the study groups. The drug vials will be concealed by uniform labels and separated and administered by coding system.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Research Ethics Committees of National Research Institute of Tuberculosis and Lung Diseases-Shahid B

Street address

Masih Daneshvari Hospital, Shahid Bahonar Street (Niyavaran), Darabad.

City

Tehran

Province

Tehran

Postal code

1956944413

Approval date

2021-08-15, 1400/05/24

Ethics committee reference number

IR.SBMU.NRITLD.REC.1400.025

Health conditions studied

1

Description of health condition studied

COVID-19 pneumonia

ICD-10 code

U07.1

ICD-10 code description

COVID-19, virus identified

Primary outcomes

1

Description

Time to clinical improvement

Timepoint

Daily until day 5

Method of measurement

Six-category ordinal scale

Secondary outcomes

1

Description

Length of hospital stay

Timepoint

Daily until discharge

Method of measurement

Medical record

2

Description

Number of days admitted to critical care unit

Timepoint

Daily until discharge

Method of measurement

Medical record

3

Description

Length of time in which patient needs oxygen therapy

Timepoint

Daily until discharge

Method of measurement

Medical record

4

Description

Length of time in which patient needs mechanical ventilation

Timepoint

Daily until discharge

Method of measurement

Medical record

5

Description

Mortality

Timepoint

Daily until discharge

Method of measurement

Medical record

Intervention groups

1

Description

Intervention group: 60 patients will receive remdesivir (Veklury) 200 mg day one then 100 mg day 2 to 5.

Category

Treatment - Drugs

2

Description

Intervention group: 60 patients will receive generic (Ronak Daru) remdesivir 200 mg day one then 100 mg day 2 to 5.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center**Name of recruitment center**

Masih Daneshvari Hospital

Full name of responsible person

Farzaneh Dastan

Street address

Masih Daneshvari Hospital, Shahid Bahonar Street (Niyavaran), Darabad.

City

Tehran

Province

Tehran

Postal code

1956944413

Phone

+98 21 2712 3000

Email

f_dastan@sbmu.ac.ir

Sponsors / Funding sources

1

Sponsor**Name of organization / entity**

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Afshin Zarghi

Street address

3rd floor, School of Medicine, Evin St, Shahid Chamran Highway

City

Tehran

Province

Tehran

Postal code

1983963113

Phone

+98 21 23871

Email

mpd@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

Hamidreza Jamaati

Position

Professor

Latest degree

Subspecialist

Other areas of specialty/work

Internal Medicine

Street address

Masih Daneshvari Hospital, Shahid Bahonar Street
(Niyavaran), Darabad.

City

Tehran

Province

Tehran

Postal code

1956944413

Phone

+98 21 2712 2020

Email

hamidjamaati@hotmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Farzaneh Dastan

Position

Assistant Professor

Latest degree

Ph.D.

Other areas of specialty/work

Medical Pharmacy

Street address

Faculty of Pharmacy, Shahid Beheshti University of
Medical Sciences, Intersection of Niyayesh Highway,
Valieasr St.

City

Tehran

Province

Tehran

Postal code

1991953381

Phone

+98 21 8820 0118

Email

f_dastan@sbmu.ac.ir

Person responsible for updating data

Contact

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Zahra Mirshafiei Langari

Position

Hospital pharmacist

Latest degree

Medical doctor

Other areas of specialty/work

Medical Pharmacy

Street address

Dr. Masih Daneshvari Hospital, Daar-Abad, Niavaran

City

Tehran

Province

Tehran

Postal code

19569-44413

Phone

+98 21 2712 2066

Email

z.mirshafiei@gmail.com

Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is 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

Title and more details about the data/document

All potential data can be shared after blinding

When the data will become available and for how long

Six months after publishing the results

To whom data/document is available

Researchers working in academic institutions

Under which criteria data/document could be used

For research purposes and meta-analysis studies

From where data/document is obtainable

Dr. farzaneh Dastan, Dr. Masih Daneshvari Hospital,
Daar-Abad, Niavaran

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

Official letter to the researchers through Email
(fzh.dastan@gmail.com).

Comments