Clinical Trial Protocol
Iranian Registry of Clinical Trials

30 May 2026

A single-arm multicenter clinical trial to evaluate the safety and efficacy of Remdesivir in COVID-19 patients with progressive severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2)

Protocol summary

Study aim

The aim of the study is to evaluate the safety and efficacy of Remdesivir in the treatment of COVID-19

Design

This study is a single-arm, uncontrolled, open-label clinical trial to evaluate the safety and efficacy of Remdesivir in COVID-19 patients.

Settings and conduct

This multicenter, single-arm, open-label clinical trial will be carried out from March 20, 2020, in different medical universities of Iran. Each recruitment center consecutively enrolls between 5 and 10 eligible patients who meet the eligibility criteria and sign the informed consent by themselves or their guardians (in case of decreased level of consciousness or cognitive impairment). Eligible patients are followed for 14 days (from the beginning of the intervention). Each hospital will report its findings to the DSMB after the enrolling of the three patients. They may enroll subsequent patients, after obtaining authorization from DSMB. Primary outcomes and serious adverse events (SAEs) will be received daily. Secondary outcomes and paraclinical and radiologic details of patients will be obtained through hospital records (due to the workload of centers).

Participants/Inclusion and exclusion criteria

Inclusion criteria: All confirmed COVID-19 patients who are still progressing despite receiving standard treatment. Exclusion criteria: Different treatment with national protocol, under mechanical ventilation and evidence of multiple organ failure.

Intervention groups

Patients in the intervention group receive remdesivir (200 mg on the first day followed by 100 mg per day) in addition to the standard treatment

Main outcome variables

TTCI: time (day) to clinical improvement (2 score improvement of six categorical scores ranging from death to complete recovery) and TTCR: time (hr) to the normalization of fever, respiration, cough, and blood oxygen level is considered as the primary outcomes of this study.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20171122037571N2**
Registration date: **2020-04-12, 1399/01/24**
Registration timing: **registered_while_recruiting**

Last update: **2020-04-12, 1399/01/24**
Update count: **0**

Registration date

2020-04-12, 1399/01/24

Registrant information

Name

Hamed Hosseini

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 8670 5503

Email address

hmdhosseini@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-03-20, 1399/01/01

Expected recruitment end date

2020-05-19, 1399/02/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

A single-arm multicenter clinical trial to evaluate the safety and efficacy of Remdesivir in COVID-19 patients with progressive severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2)

Public title

Remdesivir in treatment of COVID-19

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Ablility to fully understand, willingness to participate, and signing the informed consent form (in case of decreased level of consciousness or/ and cognitive impairment, informed consent is obtained from their legal representative) Ages over 18 years Patients with a definitive diagnosis of SARS-CoV-2 virus based on PCR with specific pulmonary involvement in radiography who have progressive hospital course (SpO2 <85% or RR > 30) despite receiving standard of care treatment protocols within 72 hours

Exclusion criteria:

Participants in any other clinical trial for COVID-19 Concomitant treatment with other antiviral drugs other than those recommended in the national protocol Patients undergoing mechanical ventilation at the time of baseline Evidence of multiorgan failure in the patient's clinical record based on the physician's diagnosis Alanine aminotransferase (ALT) or aspartate aminotransferase (AST) above 5 times the upper limit of normal (ULN) Creatinine clearance less than 50 ml/min The presence of any concurrent major diseases including malignancy, advanced heart failure, cirrhosis, chronic kidney disease, stroke, Alzheimer's, chronic progressive neurological diseases, etc. Pregnant and lactating women Possibility of being transferred to another hospital with no access to the study drug (for any reason)

Age

From **18 years** old

Gender

Both

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: **120**

Randomization (investigator's opinion)

N/A

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Single

Other design features

Medicine used in study was provided by International donation as Compassionate use under the supervision of the Ministry of Health and Medical Education. The study was approved by the TUMS ethics committee and received a Clinical Trial Authorization- CTA from the Food and Drug Administration before the study began.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Tehran University of Medical Sciences

Street address

Room 105 , 5th floor, Central construction of Tehran University of Medical Sciences, Ghods intersection, Keshavarz blvd.

City

Tehran

Province

Tehran

Postal code

1417653761

Approval date

2020-03-17, 1398/12/27

Ethics committee reference number

IR.TUMS.VCR.REC.1398.1076

Health conditions studied

1

Description of health condition studied

COVID-19

ICD-10 code

U07.1

ICD-10 code description

Clinically-epidemiologically diagnosed COVID-19, Probable COVID-19, Suspected COVID-19

Primary outcomes

1

Description

Time to Clinical Improvement (TTCI): TTCI is defined as the time (in days) from initiation of study treatment until a decline of two categories from admission status on a six-category ordinal scale of clinical status which ranges from 1 (discharged) to 6 (death).6. Death; 5. ICU, requiring ECMO and/or IMV; 4. ICU/hospitalization, requiring NIV/ HFNC therapy;3. Hospitalization, requiring supplemental oxygen (but not NIV/ HFNC);2. Hospitalization, not requiring supplemental oxygen; 1.

Hospital discharge. IMV, invasive mechanical ventilation; NIV, non-invasive mechanical ventilation;HFNC, High-flow nasal cannula.

Timepoint

Daily for 14 days

Method of measurement

Based on clinical evaluation

2

Description

Time to Clinical recovery (TTCR): TTCR is defined as the time (in hours) from initiation of study treatment until normalization of fever, respiratory rate, and oxygen saturation, and alleviation of cough sustained for at least 72 hours.Normalization and alleviation criteria:• Fever - ≤36.9°C or -axilla, ≤37.2 °C oral,• Respiratory rate - ≤24/minute on room air,• Oxygen saturation - >94% on room air,• Cough - mild or absent on a patient-reported scale of severe, moderate, mild, absent.

Timepoint

Daily for 14 days

Method of measurement

Based on clinical evaluation

Secondary outcomes

1

Description

Percentage of patients with improved oxygen supply: Percentage of patients with improved oxygen supply (at least one step in reducing oxygen supply) including 1-no need for additional oxygen supply. 2. Nasal oxygen catheter inhalation 3. Oxygen inhalation with mask. 4-NIV 5- Ventilator

Timepoint

Daily for 14 days

Method of measurement

Based on clinical evaluation

2

Description

PaO2 / FiO2 ratio: lowest fraction recorded in a day

Timepoint

Daily for 14 days

Method of measurement

Oximeter

3

Description

The extent of lung involvement in CT scan

Timepoint

At baseline and 14th day

Method of measurement

Radiologist report basis

4

Description

Any adverse event

Timepoint

During the study period

Method of measurement

Any events during the study according to the patient's report or physician's judjment

5

Description

All cause mortality

Timepoint

During the 28 days after starting the intervention

Method of measurement

Hospital death record or statement by relatives after discharge

Intervention groups

1

Description

Intervention group: In addition to standard treatment:(two-drug regimen including 500 mg chloroquine phosphate / 400 mg hydroxychloroquine sulfate; single-dose and lopinavir/ritonavir 400/100 mg BID for at least 5 days or alternatively, atazanavir OR three-drug regimen including 500 mg chloroquine phosphate / 400 mg hydroxychloroquine sulfate; single-dose and lopinavir/ritonavir 400/100 mg BID for at least 5 days and ribavirin 1200 mg BID for at least 5 days)Remdesivir is also prescribed for 5 days (for patients over 40 kg or more: Amp Remdesivir 200 mg IV infusion over 30 minutes once-daily dose, followed by 100 mg iv infusion over 30 minutes once-daily maintenance doses for next 4 days.For patients weighing less than 40 kg: Amp Remdesivir 5 mg/kg IV infusion over 30 minutes loading dose on day 1, followed by 2.5 mg/kg iv infusion over 30 minutes once-daily maintenance doses for next 4 days)

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Khomeini Hospital

Full name of responsible person

Mohammad Reza Salehi

Street address

Imam Khomeini Hospital, Keshavarz Blvd at Gharib St., Tehran, Iran

City

Tehran

Province

Tehran

Postal code

1419733141

Phone

+98 21 8896 3546

Email
ctc@tums.ac.ir
Web page address
http://ikhc.tums.ac.ir/

2

Recruitment center
Name of recruitment center
Masih Daneshvari
Full name of responsible person
Payam Tabarsi
Street address
Daar Abad, Niavaran, Masih Daneshvarai Hospital
City
Tehran
Province
Tehran
Postal code
1956944413
Phone
+98 21 2610 6000
Fax
+98 21 2610 9680
Email
pr.nritld@sbmu.ac.ir
Web page address
https://nritld.sbmu.ac.ir/index.jsp?fkeyid=&siteid=200&pageid=1419

3

Recruitment center
Name of recruitment center
Sina Hospital
Full name of responsible person
Azar Haddadi
Street address
Sina Hospital, Hasan Abad Square, Tehran, Iran
City
Tehran
Province
Tehran
Postal code
1136746911
Phone
+98 21 6634 8500
Fax
+98 21 6634 8553
Email
Hadadiaz@tums.ac.ir
Web page address
http://sinahospital.tums.ac.ir/

4

Recruitment center
Name of recruitment center
Baqiyatallah Hospital
Full name of responsible person
Mostafa Ghanei
Street address
Baqiyatallah Hospital, Mulla Sadra Street, Vanak Square, Tehran, Iran.,
City
Tehran
Province
Tehran
Postal code
1435915371
Phone
+98 21 8805 0436
Fax
+98 21 8805 0436
Email
m.ghanei@bmsu.ac.ir
Web page address
https://baq.bmsu.ac.ir/Portal/home/?283090/english

5

Recruitment center
Name of recruitment center
Rasool Akram Hospital
Full name of responsible person
Saeed Kalantari
Street address
Hazrate Rasoole Akram Hospital,Niayesh St,Satarkhan Av, Tehran, IRAN
City
Tehran
Province
Tehran
Postal code
1449614535
Phone
+98 21 6435 2564
Fax
+98 21 6650 2248
Email
kalantari.s@iums.ac.ir
Web page address
https://hrmc.iums.ac.ir/

6

Recruitment center
Name of recruitment center
Loghman Hospital
Full name of responsible person
Ilad Alavi Darazam
Street address
Makhsoos St, South Karegar Ave, Tehran, Iran
City
Tehran
Province
Tehran
Postal code
1333635445
Phone
+98 21 5541 9005
Fax
+98 21 5541 7547
Email
Ilad13@yahoo.com
Web page address

http://lhmc.sbmu.ac.ir/

7

Recruitment center

Name of recruitment center
AmirAlam Hospital

Full name of responsible person
Mehrdad Hasibi

Street address
Saadi St., Enghelab St., Tehran, Iran.

City
Tehran

Province
Tehran

Postal code
1145765111

Phone
+98 21 6672 7060

Fax
+98 21 6670 4805

Email
mehrdad_hasibi@yahoo.com

Web page address
http://amiralam.tums.ac.ir/

8

Recruitment center

Name of recruitment center
Al-Zahra Hospital

Full name of responsible person
Farzin Khorvash

Street address
Al-Zahra Hospital, Soffeh Blvd, Isfahan

City
Isfahan

Province
Isfehan

Postal code
8174675731

Phone
+98 31 3620 2020

Fax
+98 31 3669 1510

Email
Farzin300@gmail.com

Web page address
http://alzahra.mui.ac.ir/

9

Recruitment center

Name of recruitment center
Imam Reza Hospital

Full name of responsible person
Rozita Khodashahi

Street address
Imam Reza Hospital, Imam Reza square, Ibne Sina Street, Mashhad, Iran

City
Mashhad

Province
Razavi Khorasan

Postal code
9137913316

Phone
+98 51 3858 3845

Fax
+98 51 3858 3845

Email
khodashahir@mums.ac.ir

Web page address
https://emamreza.mums.ac.ir/

10

Recruitment center

Name of recruitment center
Razi Hospital

Full name of responsible person
Aydin PoorKazemi

Street address
Razi Hospital, Sardar St., Rasht, Iran.

City
Rasht

Province
Guilan

Postal code
41448

Phone
+98 13 3355 0028

Fax
+98 13 3355 9787

Email
razi.hospital@yahoo.com

Web page address
http://www.gums.ac.ir/razi/default.aspx?tabid=444

11

Recruitment center

Name of recruitment center
Razi Hospital

Full name of responsible person
Farhang BabaMahmoudi

Street address
Razi Hospital, Yusef Reza St., GhaemShahr, Iran.

City
Ghaemshahr

Province
Mazandaran

Postal code
4765686743

Phone
+98 11 4221 8018

Fax
+98 11 4221 8011

Email
Farhang.baba@yahoo.com

Web page address
https://razihospital.mazums.ac.ir/

12

Recruitment center

Name of recruitment center
Beheshti Hospital
Full name of responsible person
Mansooreh Momen-Heravi
Street address
Ravandi Blvd, Beheshti Hospital, Kashan, Iran
City
Kashan
Province
Isfehan
Postal code
8715981151
Phone
+98 31 5554 0026
Fax
+98 31 5554 8900
Email
mansoreheravi@yahoo.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Tehran University of Medical Sciences
Full name of responsible person
Reza Malekzadeh
Street address
Digestive Disease Research Institute, Shariati Hospital, Kargar Street, Tehran
City
Tehran
Province
Tehran
Postal code
1411713135
Phone
+98 21 8241 5000
Fax
+98 21 8241 5400
Email
info@ddri.ir
Web page address
https://ddri.ir/
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Tehran 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
Tehran University of Medical Sciences
Full name of responsible person
Hamed Hosseini
Position
Assisstant professor in Epidemiology
Latest degree
Ph.D.
Other areas of specialty/work
Epidemiology
Street address
23rd Unit, 4th Floor, No. 1547, North Kargar St.,
City
Tehran
Province
Tehran
Postal code
1417993337
Phone
+98 21 8896 3546
Fax
+98 21 8896 3546
Email
ctc@tums.ac.ir
Web page address
http://ctc.tums.ac.ir

Person responsible for scientific inquiries

Contact
Name of organization / entity
Tehran University of Medical Sciences
Full name of responsible person
Mohammad Reza Salehi
Position
Assistant Professor of Infectious Disease
Latest degree
Specialist
Other areas of specialty/work
Infectious diseases
Street address
Imam Khomeini Hospital Complex, Gharib | Keshavarz intersection, Tehran, Iran.
City
Tehran
Province
Tehran
Postal code
1419733141
Phone
0098 21 61190
Email
imamhospital@tums.ac.ir
Web page address
http://ikhc.tums.ac.ir/

Person responsible for updating data

Contact

Name of organization / entity
Tehran University of Medical Sciences

Full name of responsible person
Hamed Hosseini

Position
Associate professor in Epidemiology

Latest degree
Ph.D.

Other areas of specialty/work
Epidemiology

Street address
23 th unit, 4th floor, No 1547, North Kargar Street,

City
Tehran

Province
Tehran

Postal code
1417993337

Phone
+98 21 8896 3546

Fax
+98 21 8896 3546

Email
hmdhosseini@gmail.com

Web page address
http://ctc.tums.ac.ir

Sharing plan

Deidentified Individual Participant Data Set (IPD)
No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD
The DSMB decides how the results will be disseminated after reviewing the preliminary data.

Study Protocol
No - There is not a plan to make this available

Statistical Analysis Plan
No - There is not a plan to make this available

Informed Consent Form
No - There is not a plan to make this available

Clinical Study Report
No - There is not a plan to make this available

Analytic Code
No - There is not a plan to make this available

Data Dictionary
No - There is not a plan to make this available