Clinical Trial Protocol
Iranian Registry of Clinical Trials

06 Nov 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

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Name of organization / entity

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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

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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

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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
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
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Country of origin
Type of organization providing the funding
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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