COVID-19 is an emerging, rapidly evolving situation.
Get the latest public health information from CDC: https://www.coronavirus.gov.
Get the latest research information from NIH: https://www.nih.gov/coronavirus.

A Trial of Remdesivir in Adults With Severe COVID-19

The safety and scientific validity of this study is the responsibility of the study sponsor and investigators. Listing a study does not mean it has been evaluated by the U.S. Federal Government. Read our disclaimer for details.

ClinicalTrials.gov Identifier: NCT04257656

Recruitment Status : Terminated (The epidemic of COVID-19 has been controlled well in China, no eligible patients can be enrolled at present.)
First Posted : February 6, 2020
Last Update Posted : April 15, 2020

Sponsor:
Capital Medical University

Information provided by (Responsible Party):
Bin Cao, China-Japan Friendship Hospital

Study Description

Go to

Brief Summary:

In December 2019, Wuhan, in Hubei province, China, became the center of an outbreak of pneumonia of unknown cause. In a short time, Chinese scientists had shared the genome information of a novel coronavirus (SARS-CoV-2) from these pneumonia patients and developed a real-time reverse transcription PCR (real-time RT-PCR) diagnostic assay.

Given no specific antiviral therapy for COVID-19 and the ready availability of remdesvir as a potential antiviral agent, based on pre-clinical studies in SARS-CoV and MERS-CoV infections, this randomized, controlled, double blind trial will evaluate the efficacy and safety of **remdesivir** in patients hospitalized with severe COVID-19.

Condition or disease	Intervention/treatment	Phase
COVID-19 **Remdesivir** SARS-CoV-2	Drug: **Remdesivir** Drug: **Remdesivir** placebo	Phase 3

Detailed Description:

In December 2019, Wuhan, in Hubei province, China, became the center of an outbreak of pneumonia of unknown cause. In a short time, Chinese scientists had shared the genome information of a novel coronavirus (SARS-CoV-2) from these pneumonia patients and developed a real-time reverse transcription PCR (real-time RT-PCR) diagnostic assay.

Whilst the outbreak is likely to have started from a zoonotic transmission event associated with a large seafood market that also traded in live wild animals, it soon became clear that person-to-person transmission was also occurring. The number of cases of infection with COVID-19 identified in Wuhan increased markedly over the later part of January 2020, with cases identified in multiple other Provinces of China and internationally. Mathematical models of the expansion phase of the epidemic suggested that sustained person-to-person transmission is occurring, and the R-zero is substantially above 1, the level required for a self-sustaining epidemic in human populations.

The clinical spectrum of COVID-19 illness appears to be wide, encompassing asymptomatic infection, a mild upper respiratory tract infection, and severe viral pneumonia with respiratory

failure and even death. Although the per infection risk of severe disease remains to be determined, case-fatality risk of 11-14% has been reported in several initial studies of seriously ill patients and case-fatality has been estimated approximately at 2% overall. Also the large number of cases in Wuhan has resulted in a large number of patients hospitalised with pneumonia requiring supplemental oxygen and sometimes more advance ventilator support.

This new coronavirus, and previous experiences with SARS and MERS-CoV, highlight the need for therapeutics for human coronavirus infections that can improve clinical outcomes, speed recovery, and reduce the requirements for intensive supportive care and prolonged hospitalisation.

Given no specific antiviral therapy for COVID-19 and the ready availability of remdesvir as a potential antiviral agent, based on pre-clinical studies in SARS-CoV and MERS-CoV infections, this randomized, controlled, double blind trial will evaluate the efficacy and safety of remdesivir in patients hospitalized with severe COVID-19.

Study Design

Go to

Study Type :	Interventional (Clinical Trial)
Actual Enrollment :	237 participants
Allocation:	Randomized
Intervention Model:	Parallel Assignment
Masking:	Quadruple (Participant, Care Provider, Investigator, Outcomes Assessor)
Primary Purpose:	Treatment
Official Title:	A Phase 3 Randomized, Double-blind, Placebo-controlled, Multicenter Study to Evaluate the Efficacy and Safety of **Remdesivir** in Hospitalized Adult Patients With Severe COVID-19.
Actual Study Start Date :	February 6, 2020
Actual Primary Completion Date :	March 30, 2020
Actual Study Completion Date :	April 10, 2020

Arms and Interventions

Go to

Arm	Intervention/treatment
Experimental: **Remdesivir** group active **remdesivir**	Drug: **Remdesivir**

Arm	Intervention/treatment
	RDV 200 mg loading dose on day 1 is given, followed by 100 mg iv once-daily maintenance doses for 9 days. Other Name: GS-5734
Placebo Comparator: Control group Placebos matched **remdesivir**	Drug: **Remdesivir** placebo RDV placebo 200 mg loading dose on day 1 is given, followed by 100 mg iv once-daily maintenance doses for 9 days.

Outcome Measures

Go to

Primary Outcome Measures :

1. Time to Clinical Improvement (TTCI) [Censored at Day 28] [Time Frame: up to 28 days]

   The primary endpoint is time to clinical improvement (censored at Day 28), defined as the time (in days) from randomization of study treatment (**remdesivir** or placebo) until a decline of two categories on a six-category ordinal scale of clinical status (1 = discharged; 6 = death) or live discharge from hospital.

   Six-category ordinal scale:

   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 or meet discharge criteria (discharge criteria are defined as clinical recovery, i.e. fever, respiratory rate, oxygen saturation return to normal, and cough relief).

   Abbreviation: IMV, invasive mechanical ventilation; NIV, non-invasive mechanical ventilation; HFNC, High-flow nasal cannula.

Secondary Outcome Measures :

1. Clinical status [Time Frame: days 7, 14, 21, and 28]

   Clinical status, assessed by the ordinal scale at fixed time points (days 7, 14, 21, and 28).

2. Time to Hospital Discharge OR NEWS2 (National Early Warning Score 2) of ≤ 2 maintained for 24 hours. [Time Frame: up to 28 days]

   Time to Hospital Discharge OR NEWS2 (National Early Warning Score 2) of ≤ 2 maintained for 24 hours.

3. All cause mortality [Time Frame: up to 28 days]
4. Duration (days) of mechanical ventilation [Time Frame: up to 28 days]
5. Duration (days) of extracorporeal membrane oxygenation [Time Frame: up to 28 days]
6. Duration (days) of supplemental oxygenation [Time Frame: up to 28 days]
7. Length of hospital stay (days) [Time Frame: up to 28 days]
8. Time to 2019-nCoV RT-PCR negativity in upper and lower respiratory tract specimens [Time Frame: up to 28 days]
9. Change (reduction) in 2019-nCoV viral load in upper and lower respiratory tract specimens as assessed by area under viral load curve. [Time Frame: up to 28 days]
10. Frequency of serious adverse drug events [Time Frame: up to 28 days]

Eligibility Criteria

Go to

Information from the National Library of Medicine

Choosing to participate in a study is an important personal decision. Talk with your doctor and family members or friends about deciding to join a study. To learn more about this study, you or your doctor may contact the study research staff using the contacts provided below. For general information, Learn About Clinical Studies.

Ages Eligible for Study: 18 Years and older (Adult, Older Adult)

Sexes Eligible for Study:	All
Accepts Healthy Volunteers:	No

Criteria

Inclusion Criteria:

1. Age ≥18 years at time of signing Informed Consent Form
2. Laboratory (RT-PCR) confirmed COVID-19.
3. Lung involvement confirmed with chest imaging
4. Hospitalized with a SaO2/SPO2≤94% on room air or Pa02/Fi02 ratio <300mgHg
5. ≤12 days since illness onset
6. Willingness of study participant to accept randomization to any assigned treatment arm.
7. Must agree not to enroll in another study of an investigational agent prior to completion of Day 28 of study.

Exclusion Criteria:

1. Physician makes a decision that trial involvement is not in patients' best interest, or any condition that does not allow the protocol to be followed safely.
2. Severe liver disease (e.g. Child Pugh score ≥ C, AST>5 times upper limit)
3. Pregnant or breastfeeding, or positive pregnancy test in a predose examination
4. Patients with known severe renal impairment (estimated glomerular filtration rate ≤30 mL/min/1.73 m2) or receiving continuous renal replacement therapy, hemodialysis, peritoneal dialysis
5. Will be transferred to another hospital which is not the study site within 72 hours.
6. Receipt of any experimental treatment for COVID-19 within the 30 days prior to the time of the screening evaluation.

Contacts and Locations

Go to

Information from the National Library of Medicine

To learn more about this study, you or your doctor may contact the study research staff using the contact information provided by the sponsor.

Please refer to this study by its ClinicalTrials.gov identifier (NCT number): ***NCT04257656***

Locations

China, Beijing

Bin Cao
Beijing, Beijing, China, 100029

Sponsors and Collaborators

Capital Medical University

More Information

Go to

Responsible Party:	Bin Cao, Professor, China-Japan Friendship Hospital
ClinicalTrials.gov Identifier:	NCT04257656 History of Changes
Other Study ID Numbers:	CAP-China **remdesivir** 2
First Posted:	February 6, 2020 Key Record Dates
Last Update Posted:	April 15, 2020
Last Verified:	April 2020

Individual Participant Data (IPD) Sharing Statement:

Plan to Share IPD:	Undecided

Studies a U.S. FDA-regulated Drug Product:	No
Studies a U.S. FDA-regulated Device Product:	No