(https://www.coronavirus.gov)
(https://www.nih.gov/coronavirus)

National Institute of Allergy and Infectious Diseases

# Adaptive COVID-19 Treatment Trial (ACTT)

NIAID is supporting a randomized, controlled clinical trial to evaluate the safety and efficacy of the investigational antiviral remdesivir in hospitalized adults diagnosed with coronavirus disease 2019 (COVID-19). It will take place in up to 75 locations globally.

Remdesivir, developed by Gilead Sciences Inc., is an investigational broad-spectrum antiviral treatment. It was previously tested in humans with Ebola virus disease and has shown promise in animal models for treating Middle East respiratory syndrome (MERS) (/node/12452) and severe acute respiratory syndrome (SARS), which are caused by other coronaviruses.

## What does the study involve?

All potential participants will undergo a baseline physical exam before receiving treatment. Eligible study participants will then be randomly assigned either to the investigational treatment group or the placebo group. The study is double-blind, meaning trial investigators and participants would not know who is receiving remdesivir or placebo. Participants in the investigational treatment group will receive 200 milligrams (mg) of remdesivir intravenously on the first day of enrollment to the study. They will receive another 100 mg each day for the duration of hospitalization, for up to 10 days total. The placebo group will receive, at an equal volume, a solution that resembles remdesivir but contains only inactive ingredients.

Clinicians will regularly monitor participants and will assign them daily scores based on a predefined scale of clinical outcomes that considers factors such as temperature, blood pressure, and use of supplemental oxygen, among others. Participants also will be asked to provide blood samples and nose and throat swabs approximately every two days. Researchers will test these specimens for SARS-CoV-2.

## Who can participate?

Participants in the NIH-sponsored trial must have laboratory-confirmed SARS-CoV-2 infection and evidence of lung involvement, including rattling sounds when breathing (rales) with a need for supplemental oxygen or abnormal chest X-rays, or illness requiring mechanical ventilation. Individuals with confirmed infection who have mild, cold-like symptoms or no apparent symptoms will not be included in the study. In accordance with standard clinical research protocols, eligible patients will provide informed consent to participate in the trial.

## Where is it taking place?

There are currently 39 sites participating in this trial. A list can be found on ClinicalTrials.gov under locations (https://clinicaltrials.gov/ct2/show/NCT04280705#contacts) .

# More information

- Visit ClinicalTrials.gov and search identifier NCT04280705 (https://clinicaltrials.gov/ct2/show/NCT04280705) .
- NIAID News Release: NIH Clinical Trial of Remdesivir to Treat COVID-19 Begins (https://www.niaid.nih.gov/node/12511/)

# Participating in Research

Watch a series of short informational videos (http://www.hhs.gov/ohrp/education-and-outreach/about-research-participation/informational-videos/index.html) about participating in clinical trials. These videos are intended to help potential participants understand how research works, what questions they should consider asking, and things to think about when deciding whether or not to participate in a study.

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