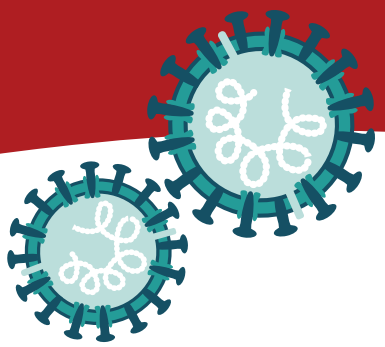
GS-US-540-9012

Cherokee Nation IRB Approved: 28Jan2021

Have you or a family member tested positive for COVID-19 and would be interested in participating in an important research study?



Cherokee Nation Health Services is currently enrolling participants.

You may qualify if you:

- Are at least 18 years old
- Have laboratory-confirmed SARS-COV-2 infection
- Have COVID-19 symptoms such as fever, cough, sore throat and do not require hospitalization
- Are currently not hospitalized, OR have not been previously hospitalized due to COVID-19

Physician: **Jorge Mera, MD**
Cherokee Nation Outpatient Health Center
19600 E. Ross St., Tahlequah, OK 74464

For more information, please call us at 918-316-2379 .

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FACT SHEET
A Phase 3 Randomized, Double-Blind Placebo-Controlled Trial to Evaluate the Efficacy and Safety of Remdesivir (GS-5734TM) Treatment of COVID-19 in an Outpatient Setting

This Fact Sheet contains information to help you understand the potential risks and benefits of participating in a multicenter clinical study.

Background

While information so far suggests that most COVID-19 illness is mild, serious illness can occur resulting in worsening of pre-existing health conditions or even death. Elders and people of all ages with severe, long-lasting (chronic) medical conditions like heart disease, lung disease, and diabetes, for example, seem to be at higher risk of being hospitalized for COVID-19. In addition, American Indians/Alaska Natives (AI/AN) have the highest hospitalization rates due to COVID-19 compared to other ethnic groups in the US. [1]

What is remdesivir?

Remdesivir is an antiviral medicine that is being investigated for the treatment of COVID-19. Remdesivir is given intravenously (IV) once a day.
The safety and effectiveness of using remdesivir to treat people with COVID-19 who do not require hospitalization is currently being researched. The most frequent reported side effects are nausea and elevated liver enzymes. Side effects that are not known could also occur. The Cherokee Nation is among 150 locations worldwide that was contacted and selected by Gilead Sciences, Inc. to participate in a clinical trial that will be evaluating the antiviral drug, remdesivir.

What is the study addressing?

The proposed study is evaluating the safety and benefit of remdesivir for the treatment of patients with COVID-19 in an outpatient setting. Cherokee Nation is participating in a study to evaluate remdesivir in an outpatient setting. The trial aims to measure whether remdesivir for 3 days given into a vein in an outpatient setting is an effective treatment compared to placebo in decreasing the risk of hospitalization and death in patients who test COVID-19 positive in a clinical setting, but have indicators for underlying health conditions and at-risk for disease progression.

Who can participate?

Only 18 years and older Native American patients who are recently diagnosed with COVID-19 and who have underlying health conditions can choose to participate.

What happens if you participate?

Your study doctor will discuss all appropriate treatment options and the risks and benefits with you. You can discuss if you want to have any treatment or if you want to choose another treatment such as having only standard of care treatments for your infection. These treatments include those that are already approved by FDA. If you decide to participate in this study it is important that you are aware that enrollment into this study is voluntary, requires informed consent and is free of charge. You may leave the study at any time without giving a reason and this will not affect medical care which you would otherwise receive. This is a randomized, double-blind, placebo-controlled, multicenter study. Randomized means the study treatment you take will be chosen by chance - like flipping a coin. You will have 1 out of 2 chances to receive remdesivir and 1 out of 2 chances to receive placebo. Double-blind means you and your study doctor will not know what study drug you will be taking. Placebo means that you may be receiving an infusion with no medicine in it but that looks like remdesivir. If you decide to participate you will be assigned to treatment with remdesivir or placebo. It is important for you to understand that you may not personally benefit from this study and that there are some risks involved.

How long will you be on the study?

Taking part in this study will last about 28 days, not including the screening visit which can last up to 2 days. During this time, your visits will either be in the Cherokee Nation outpatient Health Center in Tahlequah or performed by a home health nurse in your home via telehealth, virtually.

Where can you find more information about the study?

A description of this clinical trial will be available on http://www.ClinicalTrials.gov (NCT04501952). You may also contact the Cherokee Nation Health Services clinical trial team at 918-316-2379.

Goals of a clinical study

Studies are a way to see if a drug is useful in treating a disease and taking part in this study may help us know more about how to treat AI/AN people with COVID-19 infection. The CNHS participation in this study will give you the choice of participating in a clinical trial that evaluates a treatment for a disease status for which we otherwise have no treatment to offer. Cherokee Nation welcomes the opportunity to participate in scientific research that can benefit Indian Country and other vulnerable populations.

References

1. COVID-19 Hospitalization and Death by Race/Ethnicity. CDC
www.cdc.gov/coronavirus/2019-ncov/covid-data/investigations- discovery/hospitalization-death-by-race-ethnicity.html