Positive news for people who have tested positive for COVID-19.

Join a study now testing an oral medication for unvaccinated patients.

Every day, research uncovers new information about medical conditions and their treatment.

Volunteer involvement in clinical studies is a key part in the development of potential new treatments.

Results collected from clinical studies have led to numerous medications and devices becoming available to patients all over the world.

What is a clinical study?

A clinical study (also known as a clinical trial) is designed to evaluate how safe and/or effective an investigational drug is in treating a specific disease or condition. An investigational drug is a substance that has been tested in the laboratory and has not been approved by the United States Food and Drug Administration (FDA). The FDA uses the results of clinical studies to decide if an investigational drug should be made available to patients. Clinical studies are the only way new and better treatments can be developed to improve patient care.

Clinical studies are conducted by experienced and trained medical professionals who monitor the health of participants throughout the study. Also, every clinical study is reviewed by an Institutional Review Board (IRB), which helps ensure that the study is conducted safely and that the rights of study participants are protected.

What is the purpose of this study?

This study is testing an investigational drug called Tempol. The study will evaluate if early treatment with Tempol might prevent people who have COVID-19 and may be at a higher risk of developing severe illness from having to be hospitalized. About 248 people in the United States will take part.

What is Tempol?

Tempol is a unique antioxidant and anti-inflammatory medication that has been shown to attenuate Acute Respiratory Distress Syndrome (ARDS) in the lungs and decrease associated inflammatory cytokines (cytokine storm). ARDS is a serious consequence of COVID-19 that can be difficult to treat, even with mechanical ventilation. Tempol was originally studied by the National Cancer Institute as a drug to provide protection to certain body organs during radiation therapy for cancer. It has also been studied extensively in animals and has already been shown to be safe in multiple

Anti-inflammatory

Antioxidant

Antiviral

human clinical studies. Because of Tempol's mechanism of action, it may also prevent viral replication of the COVID-19 virus, regardless of the variant.

In this study, Tempol is provided as a capsule that is taken by mouth twice per day, once in the morning before a meal and again in the evening before a meal.

Who can be in the study?

To qualify for the study, you must:

- Have a laboratory confirmed infection of SARS-CoV-2 within the last 5 days
- Have at least moderate severity of at least two COVID-19 symptoms (e.g., stuffy or runny nose, sore throat, fever, chills or shivers, difficulty breathing, coughing, headache, tiredness, muscle aches and pains, or nausea)
- Be 18 years of age or older with at least one existing condition (hypertension, diabetes, obesity, cancer, chronic renal disease, or immunodeficiency)
- Be able to travel to a clinic and be able to swallow a capsule
- Not have had a COVID-19 vaccine
- Not have previously had another documented COVID-19 infection

Your medical history and other requirements will also be reviewed with you to determine if you may qualify.

What is involved in the study?

Participation in the study will last for up to 60 days. After an initial screening clinic visit to make sure you qualify for the study, you will begin receiving study

treatment with either Tempol or placebo. Placebo is an inactive substance that helps us better understand the effects of the investigational drug. You will attend about 6 study visits over the next month to collect blood and urine samples and to check on your health. These visits may take place in the research clinic, your home, or online. You will take the study treatment twice each day for the first 2 weeks during this period. About 6 weeks later you will have 1 final follow-up visit to check on your health.

During the study, you will use an e-diary, which is an app you will download to your own smartphone/device, to keep track of your symptoms, study treatment dosing, and to answer questions about your health. You will also be provided with a thermometer for checking your body temperature and a pulse oximeter (a small fingertip sensor that measures the oxygen level in your blood).

Why should I participate in the study?

There are very few treatment options available for people who have COVID-19. This study may lead to the development of a potential new treatment. Participants will also receive study-related care from medical professionals throughout the study.

Taking part in a clinical study is completely voluntary. If enrolled, participants can choose to leave the study at any time and for any reason.

Will the study cost anything?

You will not have to pay for the study drug, clinic visits, home health/telemedicine visits, or for the procedures needed for you to take part in this study. The sponsor of the study will pay for the costs of the study, as well as the costs of the tests and procedures needed in this study.

You will not be paid for taking part in this study.

How can I learn more about the study?

To ask questions or find out if you could participate, please contact:

EarlyCovidStudy.com