Clinical trial testing vitamin and steroid combination in sepsis patients underway at Emory

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A new clinical trial at Emory University and 45 other sites around the U.S. will test a combination of vitamins and steroids in patients diagnosed with sepsis. Sepsis is caused by the body's overwhelming and

life-threatening response to infection that can lead to tissue damage, organ failure and death.

According to sepsis researchers, sepsis can account for 30 to 50 percent of all hospital deaths, making it the third leading cause of death in the U.S. Those numbers also make sepsis the most expensive reason for hospitalization, with annual expenditures exceeding $20 billion.

The VICTAS Study, which stands for VItamin C, Thiamine (also known as vitamin B1) And Steroids in Sepsis, is a multi-center, randomized, placebo-controlled, double-blind clinical trial. When a patient diagnosed with sepsis is hospitalized at one of the clinical trial sites, they will be assessed for the VICTAS trial and with their consent or consent from a family member, will be randomly selected to receive the vitamin/steroid cocktail or a placebo, in addition to clinical care provided by the treating team. The doctor, patient and family members will not know whether the patient received treatment or placebo until the end of the study. Study participants will be administered the combination therapy or a placebo for four days, or until discharged from the intensive care unit (ICU), whichever comes first.

"The primary goals of this phase III study are to demonstrate the efficacy of combination therapy 1) in reducing the duration of cardiovascular and respiratory organ dysfunction or failure and 2) in reducing 30-day mortality in critically ill patients with sepsis," says Jon Sevransky, MD, MHS, FCCM, principal investigator of the multi-centered VICTAS Study and professor of medicine in the Division of Pulmonary, Allergy, Critical Care and Sleep, Emory University School of Medicine.

"There have been more than 100 phase III clinical trials of pharmacological agents with the potential to improve sepsis outcomes, but few have worked, with only timely antibiotics demonstrating benefits

for patients," says Sevransky. "We really want and need to find a better treatment for sepsis."

In 2017, positive results were published from a small study at an academic medical center in Virginia comparing the same combination therapy as in the VICTAS trial to similar control patients who did not receive combination therapy, but further study in a rigorous, randomized control trial setting was recommended.

The ingredients in the clinical trial's combination therapy include three inexpensive and readily available drugs found in hospital settings worldwide. Those factors help make this clinical trial appealing, according to researchers.

"We are familiar with the response of each of these drugs when treating patients diagnosed with sepsis," says David Wright, MD, professor and interim chair of the Department of Emergency Medicine at Emory and VICTAS co-principal investigator. "Vitamin C is a well-known antioxidant that reduces oxidative damage in the body. Patients with sepsis are known to have thiamine deficiency, so giving replacement thiamine can help strengthen the body. And we know corticosteroids play an important role in reducing inflammation in the body. Now, we will study how patients respond when using a combination of all three."

Researchers say there are very few side effects related to the three medications, making the combination therapy safer and more convenient to test in a large population of people.

More information: Vitamin C, Thiamine, and Steroids in Sepsis (VICTAS): clinicaltrials.gov/ct2/show/NC … 350?cond=NCT03509350