

## Medical discovery for sepsis moves to next phase of human trials

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Florey scientists made a special formulation of sodium ascorbate to treat sepsis. Credit: The Florey

Scientists at The Florey have proven that a formulation they pioneered alleviates deadly sepsis, with the next phase of clinical trials to start rolling out across Australia next month.

Promising results from an initial clinical trial at the Austin Hospital in



Melbourne, <u>published today</u> in *Critical Care*, show that sodium ascorbate—a pH-balanced formulation of vitamin C—is effective in treating <u>sepsis</u>.

Lead investigator Associate Professor Yugeesh Lankadeva said sepsis is notoriously difficult to treat and is often deadly.

"Sepsis accounts for 35–50 percent of all <u>hospital</u> deaths. It occurs when the <u>immune system</u> fails to fight off an underlying infection, causing lifethreatening falls in <u>blood pressure</u>, multiple organ failure, and death," Associate Professor Lankadeva said.

"In our trial at Austin Hospital, patients were given sodium ascorbate into their bloodstream, resulting in promising improvements to multiple organs."

Associate Professor Lankadeva, who is research lead of The Florey's Systems Neuroscience Theme, said the next phase of the research project will be offered in <u>intensive care</u> units in Adelaide, Melbourne, Perth, Brisbane, Alice Springs and Sydney.

"We'll recruit 300 adult septic patients to receive either our formulation or a placebo as well as normal hospital care. The results will help us gather data to determine the effectiveness of our formulation," Associate Professor Lankadeva said.

Austin Hospital's Director of Intensive Care Research, Professor Rinaldo Bellomo, said the previous part of the trial in his department involved 30 adult sepsis patients between October 2020 and November 2022.

While receiving hospital intensive care, half the patients were randomly allocated to receive sodium ascorbate, and the other half a placebo. The study found that patients with sepsis who received the sodium ascorbate



treatment:

- produced more urine, a sign of improved kidney function
- required less of the clinically used drug, noradrenaline, to restore blood pressure
- showed signs of improved function in multiple organs.

"Sepsis is the biggest killer in intensive care units in Australia and worldwide," Professor Bellomo said. "It often develops so quickly that patients are already critically ill by the time they reach us. A treatment that acts quickly, is safe and highly effective would be an absolute gamechanger."

Senior Florey researcher on the project, Professor Clive May, has spent more than 20 years investigating how sepsis causes organ failure, particularly in the brain and kidneys.

"Through our showing reduced levels of oxygen in tissues in sepsis, we identified sodium ascorbate as a possible treatment. We've seen dramatic results in our work with preclinical studies, where an extremely high dose of sodium ascorbate resulted in full recovery within just three hours, with no side effects. It's heartening to see all those years of painstaking research pay off with a treatment now within reach for patients," Professor May said.

**More information:** Fumitaka Yanase et al, Mega-dose sodium ascorbate: a pilot, single-dose, physiological effect, double-blind, randomized, controlled trial, *Critical Care* (2023). DOI: 10.1186/s13054-023-04644-x

Provided by University of Melbourne



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