

Multicenter NIH clinical trial will study potential benefits of brain cooling after a stroke

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Researchers at Cedars-Sinai Medical Center in Los Angeles, the University of California, San Diego School of Medicine, and UTHealth's Medical School will collaborate on the largest clinical trial of hypothermia (brain cooling) for stroke to date.

The ICTuS 2 study (Intravascular Cooling for [Acute Stroke](#)) will be led by overall principal investigator Patrick D. Lyden, M.D., former director of the UC San Diego Stroke Center and currently chairman of the Department of Neurology at Cedars-Sinai. Principal investigators at UC San Diego School of Medicine and The University of Texas Health Science Center at Houston (UTHealth) are Thomas Hemmen, M.D., Ph.D., director of the UCSD Stroke Center, and James C. Grotta, M.D., chairman of the Department of Neurology at UT Health, respectively.

Set to begin later this Spring, the three-and-a-half-year study will enroll 400 patients and is funded by two grants from the National Institute of Neurological Disorders and Stroke (NINDS), part of the National Institutes of Health. A UC San Diego grant includes funding for 18 study sites, while a UTHealth grant will fund eight sites. Most of the sites are in the United States, but some are in Europe.

Brain cooling has been shown to decrease brain swelling and reduce loss of neurologic function after an acute stroke. It has also been proven highly effective in saving lives and preventing neurologic damage after

cardiac arrest and after [oxygen deprivation](#) in newborns. This trial will look specifically at whether hypothermia can be used safely in elderly stroke patients.

"We know hypothermia works," said Lyden, "but is it safe when you consider age and other conditions such as diabetes or hypertension?"

In the ICTuS 2 trial, investigators will use an endovascular temperature modulation system from Philips Healthcare. Endovascular cooling provides rapid heat exchange and very fast cooling toward target temperature; in awake patients, endovascular cooling is generally superior to cooling blankets or ice packs in maintaining tight temperature control around the target temperature.

Cooling is achieved by inserting a special catheter into the inferior vena cava - the body's largest vein. No fluid enters the patient; instead, an internal circulation within the catheter transfers heat out. Study participants are covered with a warming blanket to "trick" the body into feeling warm, and temperature sensors in the skin and a mild sedative help suppress shivering. In this study, body temperature will be cooled to 33 degrees C and maintained at that level for 24 hours.

At the conclusion of the cooling period, participants will be re-warmed over 12 hours.

ICTuS 2 is a single-blind, randomized, placebo-controlled trial. To be included, patients must meet certain age and medical criteria, treatment must begin within three hours of [stroke](#) onset, and patients must receive intravenous injection of tissue plasminogen activator (tPA), a "clot-busting" medication.

Provided by Cedars-Sinai Medical Center

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