# Largest study of therapeutic cooling to reduce brain injury after stroke is now underway

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The largest clinical trial of therapeutic brain cooling (hypothermia) after stroke has launched, led by researchers at the University of California, San Diego, the University of Texas Health Science Center at Houston, and at Cedars-Sinai Medical Center in Los Angeles.

This study looks at whether hypothermia can safely be used in elderly stroke patients. In earlier studies, brain cooling decreased brain swelling after an acute stroke. It also saved lives and prevented neurological damage after cardiac arrest and after oxygen deprivation in newborns.

"We know hypothermia works, but is it safe when you consider age and other conditions such as diabetes or hypertension?" said Patrick D. Lyden, M.D., former director of the UC San Diego Stroke Center who now serves as the chairman of the Department of Neurology at Cedars-Sinai. He is the study's overall principal investigator.

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, are the principal investigators at their sites.

The study employs an advanced temperature modulation system that provides quick and controlled cooling. A metallic cooling catheter is inserted into the body's largest vein, the inferior vena cava. No fluid enters the patient, but fluid circulating inside the catheter transfers heat

out.

Study participants are covered with warming blankets to trick the body into feeling warm, which together with a mild sedative helps suppress shivering. In this study, body temperature will be cooled to 33 degrees C (about 91 degrees F) and maintained at that level for 24 hours. Participants then will be gradually rewarmed over 12 hours.

Philips Healthcare, the InnerCool system's developer, is providing the equipment and catheters

The study, ICTuS 2/3 (Phase 2/3 Study of Intravenous Thrombolysis and Hypothermia for Acute Treatment of Ischemic Stroke), will enroll 400 patients at up to 26 sites in the United States and Europe and is sponsored by the National Institute of Neurological Disorders and Stroke (NINDS), part of the National Institutes of Health (NIH). It is a single-blind, randomized, controlled trial. To be included, patients must meet age and medical criteria, treatment must begin promptly after stroke onset, and patients must receive intravenous injection of the "clot-busting" drug tPA (tissue plasminogen activator) within 3 hours of their stroke beginning.

**More information:** More information on this trial and the Phillips InnerCool system may be found at clinicaltrials.gov/ct2/show/NCT01123161 and Philips Temperature Modulation Therapy.

Provided by Cedars-Sinai Medical Center