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UC San Diego
University Archives. RSS 6020

Largest Study of Benefits of Brain "Cooling" After a Stroke Now Underway

Researchers at the University of California, San Diego, the University of Texas Health Science Center at Houston and Cedars-Sinai Medical Center Los Angeles to Collaborate

December 7, 2010

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Researchers at the University of California, San Diego School of Medicine - along with the University of Texas (UT) Health Science Center at Houston and Cedars-Sinai Medical Center Los Angeles - have launched the largest clinical trial of hypothermia (brain cooling) for stroke to date. The ICTuS 2 study (Intravascular Cooling for Acute Stroke) will look specifically at whether hypothermia can be used safely in stroke patients who also receive the FDA-approved intravenous "clot-busting" drug called tPA (Alteplase©).

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.

"The ICTuS 2/3 study is an exciting NIH-funded effort in advancing the most promising experimental stroke therapy, induced hypothermia, from the research lab to use in patients," said Thomas Hemmen, MD, PhD, director of the UC San Diego Stroke Center. Hemmen is co-principal investigator along with James C. Grotta, MD, chairman of the Department of Neurology at UT Health, and Patrick D. Lyden, MD, chairman of the Department of Neurology at Cedars-Sinai.

The three-and-a-half-year study will enroll 400 patients. Investigators will use an advanced temperature modulation system from Philips Healthcare called InnerCool that provides rapid heat exchange and very fast cooling. In awake patients, endovascular cooling is generally considered to be 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 directly enters the patient; instead, 4 degrees C fluid circulates within the catheter, ultimately resulting in cooling of the core body temperature. Study participants are covered with a warming blanket to trick the body into feeling warm, and given a mild sedative to 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 prospective, single-blind, randomized, multi-centered 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.

ICTuS 2 is funded by two grants from the National Institute of Neurological Disorders and Stroke (NINDS), part of the National Institutes of Health. These grants are an integral part of the SPOTRIAS (Specialized Programs of Translational Research in Acute Stroke) research fund furthering research into the translation of basic science discoveries into cures.

The cooling machines and catheters are provided by Philips/Innercool through an equipment loan agreement. For more information about the study and the cooling system, please go to:

http://clinicaltrials.gov or www.philips.com/InnerCool

More information on the UCSD Stroke Center - including clinical trials - click here

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