Study of brain cooling and clot-busting drug therapy for stroke receives FDA OK to expand

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An international multicenter clinical trial led by a Cedars-Sinai neurologist on the combination of brain cooling and "clot-busting" drug therapy after stroke has received Food and Drug Administration approval to expand from 50 patients to 400.

"This approval is highly significant because, after reviewing our initial safety data, the Food and Drug Administration approved us to include more patients in our study," said Patrick D. Lyden, MD, chair of the Department of Neurology at Cedars-Sinai Medical Center and the study's overall principal investigator. Thomas Hemmen, MD, PhD, director of the University of California, San Diego Health System Stroke Center, and James C. Grotta, MD, chair of the Department of Neurology at the University of Texas Health Science Center at Houston (UTHealth), are co-principal investigators.

This study, which includes the use of intravenous tissue plasminogen activator (IV tPA), the only FDA-approved treatment for acute stroke, is the latest in a series of clinical trials on brain cooling – controlled hypothermia – to reduce neurological damage after stroke.

Researchers employ a state-of-the-art system to provide rapid heat exchange and very fast cooling, achieved by inserting a special catheter into the inferior vena cava – the body's largest vein. No fluid enters the patient; an internal circulation within the catheter absorbs the body's heat

and transfers it out to slow metabolism, keep tissue swelling in check and give the brain time to rest.

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. Body temperature is cooled to 33 degrees Celsius (about 91 degrees Fahrenheit) for 24 hours before the patient is gradually warmed.

Brain cooling has been shown to decrease brain swelling and reduce loss of neurological function after acute stroke. It also has proved highly effective in saving lives and preventing neurological damage after heart attack and after oxygen deprivation in newborns.

TPA, which must be given to a patient as quickly as possible after stroke onset, sometimes can dissolve a clot and prevent or reduce serious brain injury. Lyden, the Carmen and Louis Warschaw Chair in Neurology at Cedars-Sinai, helped lead the pivotal clinical trial of the drug that led to its approval by the FDA in 1996.

Provided by Cedars-Sinai Medical Center