

Study shows combination stroke therapy safe and effective

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The combination of the clot-busting drug tPA with an infusion of the antiplatelet drug eptifibatide dissolves blood clots safely and more quickly than tPA alone, a study led by University of Cincinnati (UC) researchers has found.

Results from the study, known as the CLEAR-ER Stroke Trial, are published online in the journal *Stroke: Journal of the American Heart Association*. UC was the coordinating center for the trial, which included nine medical centers comprising 21 hospitals.

Standard treatment for [acute ischemic stroke](#) (characterized by an obstruction to the blood flow, typically a clot), is intravenous (IV) delivery of U.S. Food and Drug Administration-approved [tissue plasminogen activator](#) (tPA) within three hours of stroke onset.

The CLEAR-ER (Combined Approach to Lysis Utilizing Eptifibatide and rt-PA in Acute Ischemic Stroke – Enhanced Regimen) trial was a phase-2 clinical trial designed to determine the safety of an enhanced dosing regimen using eptifibatide and establish evidence for a phase-3 clinical trial, which would use a larger pool of subjects. As an antiplatelet medication, eptifibatide—delivered intravenously—works together with the tPA to break up the existing clot and prevents formation of additional clots by decreasing the clumping of [blood platelets](#).

"Through our team's research efforts, we were able to determine that

eptifibatide may be safely combined with medium-dose IV tPA administered within three hours of [symptom onset](#) and that a phase-3 clinical trial is warranted," says Opeolu Adeoye, MD, UC assistant professor of [emergency medicine](#) and neurosurgery and a neurointensivist at UC Medical Center.

Adeoye was co-principal investigator along with Arthur Pancioli, MD, professor and Richard C. Levy Chair for Emergency Medicine at UC. Both Adeoye and Pancioli are members of the UC Neuroscience Institute, one of four institutes affiliated with the UC College of Medicine and UC Health

Says Pancioli: "We know that the combination of these two medications dissolves clots faster and more completely than tPA alone. Our goal is to determine if we can use this combination to improve the outcomes for acute stroke victims."

CLEAR-ER investigators enrolled 126 subjects from July 2009 to October 2012. Of those, 101 received tPA plus eptifibatide and 25 received tPA alone. As the trial was a double-blind, randomized study, neither patient nor doctor was aware if the substance administered in addition to tPA was a medication or a placebo.

Investigators examined safety at specified endpoints, watching for incidence of intracerebral hemorrhage (ICH), and 90-day outcomes using a standardized measurement tool. Of the subjects who were given tPA plus eptifibatide, 50 (49.5 percent) had what were classified as good outcomes. Those who received tPA alone had nine good outcomes (36 percent).

Safety between the two groups was shown to be comparable at 36-hour, seven-day and 90-day endpoints.

The potential next step in investigation of the enhanced regimen, a phase-3 clinical trial, would typically use a larger pool of subjects determined by data from the phase-2 trial. Phase-3 trials, the last step before marketing of a medication, typically confirm its effectiveness, monitor side effects, compare it to commonly used treatments and collect information that will allow it to be used safely.

Provided by University of Cincinnati Academic Health Center

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