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# UAMS Clinical Trial Shows Promise in New Method for Stroke Treatment

LITTLE ROCK — Professor William C. Culp, M.D., and colleagues at the University of Arkansas for Medical Sciences (UAMS) have published promising results from the first human trial of a new drug to treat strokes.

If the results of this Phase I clinical trial are repeated in the next phases, the UAMS professors could be responsible for developing a completely new method for treating strokes and significantly improving their life-altering consequences.

Their results were published in the *Journal of Vascular and Interventional Radiology*.

During a stroke, the blood supply to the brain is cut off and its cells begin to die. Clots clogging a blood vessel are a common cause. Current treatments focus on breaking up or removing the clot and restoring blood supply to the brain, but doctors must move quickly to prevent death or major debilitation. That is not always possible, especially in a rural state like Arkansas.

Culp has spent 10 years testing a different method using dodecafluoropentane emulsion (DDFPe). The drug is more efficient at carrying oxygen than a human red blood cell, and it is also smaller, on a nano-size scale. The DDFPe method allows the drug to travel past the clot, taking oxygen along with it to keep the brain alive and functioning during the stroke.

“What this drug gives us is time,” Culp said. “It stops the clock so the patient can get to the right hospital with the right expertise to restore blood flow, and that kind of time is something that more than 90% of stroke patients just don’t get.”

Culp is a professor of radiology, surgery and neurology in the UAMS College of Medicine. His UAMS co-authors are Sanjeeva Onteddu, M.D., (neurology), Aliza Brown, Ph.D., (radiology/neurology), Krishna Nalleballe, M.D., (neurology), Rohan Sharma, M.D., (neurology), Robert Skinner, Ph.D., (neurobiology/developmental

sciences), Taylor Witt, M.D., (radiology), Paula Roberson, Ph.D., (biostatistics), and James Marsh, M.D., (internal medicine).

As is typical with Phase I trials, the main objective was to demonstrate the drug's safety. However, among the 24 stroke patients tested at UAMS, not only did the researchers find that the method was safe, it was also effective. The more of the drug the patients got, the more improvement they showed.

The next step, a Phase II clinical trial, will involve many more patients, likely at different medical centers across the United States. It will confirm the drug's effectiveness on a larger scale and help identify any possible side effects. Phase III and Phase IV trials would include even more patients.

For many scientists, seeing an area of research reach the clinical trial phase can be a once-in-a-career experience.

"It's truly exciting," Culp said. "We have conducted hundreds of experiments at UAMS to prepare for our first clinical trial, and they have shown, in various models, that this method could save about 80% of an area of stroke."

There are about 800,000 stroke cases in the United States annually. Culp said that of those, 12% of those patients die and 12% suffer a major loss in ability to function and 10-15% are only able to live with constant help. Additionally, other studies have estimated that only about 10 percent of people who have a stroke actually get treatment, so the number of stroke cases could be much larger.

Culp's research is part of a larger mission at UAMS to improve stroke treatment for Arkansans.

As recently as 2015, Arkansas ranked first in the nation in per capita stroke deaths based on data from the federal Centers for Disease Control and Prevention. In 2019, Arkansas ranked seventh in the nation, and the improvement is attributed in part to the UAMS digital health stroke program, part of the UAMS Institute for Digital Health & Innovation. It provides 54 Arkansas hospitals with round-the-clock access to stroke neurologists who can quickly assess whether a stroke patient can be helped by a clot-busting drug — alteplase — that often restores complete function to the patient.

Another new treatment is mechanical thrombectomy, during which an interventional radiologist threads a device into an artery at the groin and up to the clot, inserts a stent, then removes the clot to restore blood flow. UAMS is the only hospital in Arkansas able to provide this service 24 hours a day.

The ability to offer such services is why UAMS is the only health care provider in the Arkansas certified as a Comprehensive Stroke Center by The Joint Commission. The certification is the most demanding accreditation and is designed to designate hospitals that can treat the most complex stroke cases. It also means certified hospitals can provide endovascular procedures and post-procedural care and has an Emergency Department with a dedicated stroke-focused program.

Culp envisions a future where the DDFPe method could be added to these digital health, clot-busting and mechanical thrombectomy approaches to provide the vital time necessary for more patients to receive treatment.

“Strokes are terrible, life-altering things,” Culp said. “We have improved the outcomes through our digital health programs, but there are still so many people dying, so many people not getting the treatment they need right now. There’s so much more to be done to improve the delivery of care to the people of Arkansas, and to that end, we’re excited by these results and eager to continue the clinical trial process.”

UAMS is the state’s only health sciences university, with colleges of Medicine, Nursing, Pharmacy, Health Professions and Public Health; a graduate school; hospital; a main campus in Little Rock; a Northwest Arkansas regional campus in Fayetteville; a statewide network of regional campuses; and seven institutes: the Winthrop P. Rockefeller Cancer Institute, Jackson T. Stephens Spine & Neurosciences Institute, Harvey & Bernice Jones Eye Institute, Psychiatric Research Institute, Donald W. Reynolds Institute on Aging, Translational Research Institute and Institute for Digital Health & Innovation. It is the only adult Level 1 trauma center in the state. *U.S. News & World Report* named UAMS Medical Center the state’s Best Hospital; ranked its ear, nose and throat program among the top 50 nationwide; and named six areas as high performing — cancer, colon cancer surgery, heart failure, hip replacement, knee replacement and lung cancer surgery. UAMS has 2,727 students, 870 medical residents and five dental residents. It is the state’s largest public employer with more than 10,000 employees, including 1,200 physicians who provide care to patients at UAMS, its regional campuses, Arkansas Children’s Hospital, the VA Medical Center and Baptist Health. Visit www.uams.edu or www.uamshealth.com. Find us on Facebook, Twitter, YouTube or Instagram.

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