

# A pioneering stroke treatment

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The FASTEST trial will utilize UC Health's mobile stroke unit to deliver treatment within two hours of the onset of stroke. (Note: Photo taken prior to COVID-19 pandemic.). Credit: UC Health.

For decades, University of Cincinnati researchers have been pioneers in the field of stroke research.

Joseph Broderick, MD, was part of the UC team in the late '80s that conducted breakthrough studies that led to the use of a clot-busting drug as the first proven treatment for [ischemic stroke](#), the most common form of stroke that occurs when a vessel supplying blood to the brain is obstructed.

Now, Broderick and his colleagues at UC are continuing to lead the field of research in an effort to find the first proven treatment for stroke due to intracerebral hemorrhage, when blood vessels in the brain rupture and cause bleeding in the brain. He is the contact principal investigator for a global trial called FASTEST.

## **A new treatment**

The FASTEST trial will examine the effectiveness of a drug to help "plug the leak" of bleeding in the brain from intracerebral hemorrhage, Broderick said. The drug is a clotting protein our bodies naturally make to help seal leaks from blood vessels, for example when we get a cut on our skin.

The drug "is one of the important proteins our body uses to stop the bleeding," said Broderick, professor in UC's Department of Neurology and Rehabilitation Medicine in the College of Medicine, director of the UC Gardner Neuroscience Institute and a UC Health physician. "The idea here is to give it in enough of a dose that it actually can stop the leaking from small arteries in the brain."

Time is of the essence for patients suffering hemorrhagic strokes, as Broderick said most of the leaking from the brain bleed occurs within the first couple of hours. Building off of trial data of other global [trials](#) where the drug was given up to four hours from onset, the FASTEST trial will administer the drug to patients within two hours of stroke onset.

To meet the two-hour time frame, Broderick said the trial will use mobile stroke units staffed with the needed professionals, brain imaging and medicine to deliver treatment to patients where they are having a stroke. Mobile stroke units are already deployed around Cincinnati to administer the drug effective for ischemic strokes and other treatments, but now hemorrhagic stroke patients may also be able to receive treatment.

"It's a whole team that's essentially bringing an emergency department to your doorstep, whether it's at work or home or wherever," Broderick said of mobile stroke units. "It really does decrease the time from onset of symptoms to when you're able to deliver treatment. I had a patient recently where we imaged the patient's brain in the mobile stroke unit and started treatment within 35 minutes from stroke onset. That's really fast."

Broderick said due to the time limitations, the trial will also engage in a practice known as "exception from informed consent."

"The FDA and the government gives permission for certain types of study where you have to give the treatment really, really fast, the patient is affected so severely they cannot provide consent, and you aren't able to contact a legally authorized representative of the patient to discuss consent," he said. "And if it's a drug that could benefit these patients and it meets some other criteria, we can enroll the patient in the study even if we can't initially find someone to provide consent. We then obtain consent as soon as such a person is identified."

For the "exception from informed consent" to work, Broderick said it takes a lot of effort in the community to spread the word about the trial. At UC and in the Cincinnati region, this has included small group discussions and other community education initiatives so potential patients and family members can provide input about the study and can

obtain a card which allows them to opt out of the study if they do have a brain hemorrhage in the future.

The trial will enroll more than 800 patients in approximately 100 sites including UC and other parts of the U.S., Japan, Canada and Europe. Since hemorrhagic strokes are less common and the patient needs to be given the drug within two hours, Broderick estimated the trial will take about five years to recruit all of its patients. The first patient in the trial was enrolled this past weekend at Ottawa Hospital in Canada. Kyle Walsh, MD, associate professor in the Department of Emergency Medicine, is local principal investigator for FASTEST at UC Medical Center.

Brett Kissela, MD, senior associate dean for clinical research in UC's College of Medicine, the Albert Barnes Voorheis professor and chair in the Department of Neurology and Rehabilitation Medicine and chief of research services at UC Health, noted that while uncommon, intracerebral hemorrhage is the most fatal kind of stroke, with poor outcomes for patients who survive.

"The FASTEST trial will help us to find ways to minimize damage after a hemorrhage in the brain has occurred, thus leading to better outcomes for patients if they are unlucky enough to have an intracerebral hemorrhage," Kissela said.

## **National leadership**

The FASTEST trial is funded through StrokeNet, a National Institutes of Health network of 27 regional centers and approximately 500 hospitals across the United States that serve as the infrastructure and pipeline for new potential treatments for stroke prevention, intervention and recovery research. About two-thirds of the U.S. population lives within a 65-mile radius of a StrokeNet site, Broderick said.

"The global aim of the network is to basically be a leading platform for stroke trials in the U.S. and globally," Broderick said.

Since StrokeNet was established in 2013, UC has served as the network's national coordinating center, with Broderick and Pooja Khatri, MD, professor of neurology in the Department of Neurology, currently serving as co-directors. UC was chosen based on its track record of leading and organizing innovative global stroke trials."For decades, the University of Cincinnati has been recognized as one of the international leaders in stroke care and stroke research, having defined new treatments to improve the care of stroke patients," Kissela said. "Being awarded the leadership of StrokeNet by the NIH here at UC and the UC Gardner Neuroscience Institute recognizes this track record and demonstrates the importance of our department in the national and international landscape of stroke and neuroscience research more broadly."

Broderick said that sometimes the science is the "easy part" of studies, as the coordinating center is responsible for organizing the sites that host studies, procedures, clinical trial agreements and recruitment and enrollment of participants. Having the StrokeNet infrastructure in place allows new studies to hit the ground running rather than having to start from scratch each time, he said.

With StrokeNet's national coordinating center housed in Cincinnati, UC researchers have a hand in every large multicenter stroke study funded by the National Institute of Neurological Disorders and Stroke that takes place across the country.

"If you really want to know what's going on in stroke in the United States, UC is the place to find out," Broderick said.

According to Broderick, an essential part of UC's success in stroke research has been its commitment to move research into the community

so that trials and studies occur in community hospitals in addition to the UC Medical Center.

"Patients in our community have access to literally the best research for stroke prevention treatment and recovery that there is, and that's a huge add for our community," Broderick said. "We look upon ourselves as a community resource based at the university, and I think that's why we've been successful."

Kissela said UC was one of the first stroke teams to expand to multiple disciplines, as experts from neurology, emergency medicine, neurosurgery, neuroradiology and other disciplines all collaborate together.

"This multidisciplinary approach, with truly outstanding individuals collaborating from all of these areas, have made the UC stroke team the best in the world in my opinion," Kissela said. "If I or a loved one was ever to have a stroke, I would want to be cared for by our [stroke](#) team, as there simply is no better team in the world."

Provided by University of Cincinnati

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