



# The Neuroscience Institute

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***Neuroscience Institute a leader in studying  
minimally invasive surgical approach  
to large clots following bleeding stroke***

***Mayfield Clinic's Mario Zuccarello, M.D.,  
is co-Principal Investigator of NIH trial***

CINCINNATI, Ohio - Minimally invasive brain surgery, combined with a drug known for its ability to open up an artery clogged by a blood clot in stroke patients, is being tested by The Neuroscience Institute at the University of Cincinnati and University Hospital as a possible treatment for intracerebral hemorrhage, the less common but more devastating and lethal kind of stroke. An intracerebral hemorrhage involves spontaneous bleeding and the subsequent formation of a large clot in the brain.

Bleeding strokes, which include intracerebral hemorrhage, account for about 17 percent of all strokes, according to the American Stroke Association. They strike an estimated 119,000 Americans each year.

Mario Zuccarello, M.D., professor of neurosurgery at UC and a neurosurgeon with the Mayfield Clinic, is co-Principal Investigator in the national study, which seeks to determine whether minimally invasive surgery and the clot-busting drug rt-PA can eliminate the sizeable blood clots that result from intracerebral hemorrhage. The drug is delivered directly to the clot over a period of a few days through a tiny tube placed in the brain through a one-quarter-inch incision.

The clinical trial is known as the Minimally Invasive Surgery Plus rt-PA for Intracerebral Hemorrhage Evacuation, or MISTIE. The study is sponsored by the National Institutes of Health

and will involve six centers around the United States, including Johns Hopkins Medical Center in Baltimore and Mt. Sinai Medical Center in New York. Approximately 13 to 15 patients will take part at The Neuroscience Institute at UC and University Hospital.

Under Dr. Zuccarello's direction, UC's Department of Neurosurgery is serving as the surgical Coordinating Center for the study. Department Chair Raj Narayan, M.D., in the role of Surgical Committee Chairman, is responsible for reviewing all cases performed at the six centers involved in MISTIE.

"The Neuroscience Institute's leading role in the MISTIE trial reinforces our commitment to innovative treatments and technologies in the battle against neurological disease," said John M. Tew, M.D., Clinical Director of The Neuroscience Institute. "Dr. Zuccarello continues to work at the leading edge in the application of new neurosurgical techniques for the treatment of cerebral hemorrhage and stroke."

T-PA, a pharmacological cousin of rt-PA (recombinant t-PA), has been used for years in the treatment of ischemic (or clotting) stroke, which occurs when a blood clot cuts off the oxygenated blood supply to the brain. Used within three hours or less following the onset of ischemic stroke, it enables many patients to recover without permanent disability. Neither t-PA nor rt-PA can be administered intravenously in the immediate treatment of patients who suffer a bleeding stroke because they could cause increased bleeding.

Patients who survive a bleeding stroke may require the surgical removal of blood from the brain and often suffer lasting disabilities. The MISTIE trial, a randomized study, will seek to determine whether a minimally invasive surgical procedure that preserves brain tissue while allowing the neurosurgeon to suction out the blood clot, along with rt-PA injections following surgery directly into the residual clot, is superior to standard medical treatment methods following intracerebral hemorrhage. Standard medical treatment involves using medication to control blood pressure and reduce swelling caused by blood in the brain.

To remove the blood clot the neurosurgeon makes a one-quarter-inch incision over the site of the clot, then inserts a small metal tube, or drain, into the clot. Suction is applied to remove as much of the clot as possible. If the clot is still large, the neurosurgeon replaces the metal tube with a soft rubber tube, closes up the skin around the tube, and administers rt-PA through the tube every eight hours for up to three days. The tiny drains are manufactured by Codman, a division of Johnson & Johnson.

The United States Food and Drug Administration has approved the administration of rt-PA for the treatment of heart attacks and strokes in which a blood clot is blocking a vessel, but at this time it has not approved the use of rt-PA following surgery as a treatment for patients who have suffered an intracerebral hemorrhage.

"We continue to look for new approaches to treating intracerebral hemorrhage that will be most advantageous to the patient," Dr. Zuccarello said. "Large blood clots caused by intracerebral hemorrhage can take a significant time to dissolve on their own and may lead to severe and lasting

disabilities. Furthermore, removing the blood clot in the operating room without the use of minimally invasive surgical techniques has been shown in some cases to cause more damage to the brain. We are eager to study this new method of removing and dissolving a large clot with minimally invasive surgery and carefully controlled administration of rt-PA through a precisely placed tube.”

Participants in the MISTIE trial are by definition in serious condition; hence participation is not risk-free. Without treatment, 35 percent of patients would experience a second bleeding event. Bleeding also can occur when the tube is inserted into the blood clot, when medication is given, when blood is suctioned from the tube, or when the tube is removed. Other risks include infection, a general neurological worsening, and death.

Study participants will be identified in the emergency room and randomly assigned to one of two groups. One group will receive standard treatment; the other will receive treatment with rt-PA following surgery. Participants must:

- be between the ages of 18-75
- be free of clotting disorders and/or other interfering illnesses
- be diagnosed within 24 hours
- have stabilized blood pressure
- have an intracerebral hemorrhage (as determined by CT scan) of at least 25 millimeters (about 2½ teaspoons)
- not have experienced a ruptured aneurysm or a vascular malformation that is causing bleeding in the brain.

Dr. Zuccarello has no financial interest in Codman, which manufactures the drains used in the MISTIE trial.

The Mayfield Clinic is recognized as one of the nation's leading physician organizations for clinical care, education, and research of the spine and brain. The group includes 20 neurosurgeons and treats 20,000 patients from 35 states and a dozen countries in a typical year. Mayfield's neurosurgeons are active participants in important clinical trials and have pioneered surgical procedures and instrumentation that have revolutionized the medical art of neurosurgery for brain tumors and neurovascular diseases and disorders.

The Neuroscience Institute is a collaborative effort of the University Hospital, nine academic departments at the UC College of Medicine, and independent physician practice groups. The Institute is dedicated to patient care, research, education, and the development of new medical technologies.

For more information about the ICH-MISTIE study, including complete details about eligibility, contact Suzanne Kempisty at (513) 558-5387 or [suzanne.kempisty@uc.edu](mailto:suzanne.kempisty@uc.edu)

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