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Trial on Early Intervention of Hemorrhagic Stroke Advances

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Medical device maker NICO Corp. has enrolled its first patient in a clinical trial designed to determine the procedural safety and economic and functional benefit of early surgical removal of intracerebral hemorrhage using its BrainPath Approach™.

The randomized trial, called ENRICH (**E**arly Mi**N**mally-invasive **R**emoval of **ICH**) is sponsored by Indianapolis-based NICO and led by the Emory Stroke Center of Emory University Hospitals in Atlanta and the Marcus Stroke & Neuroscience Center of Grady Memorial Hospital, also in Atlanta.

The BrainPath Approach uses a combination of technologies, including the FDA-cleared NICO BrainPath® for non-disruptive access and NICO Myriad® to achieve the goal of maximum clot evacuation.

“Our initial clinical results with this approach for early clot removal have been exciting and provided a wake-up call to what has been missing in hemorrhagic stroke care,” said Daniel Barrow, MD, chief of neurosurgery at Emory University and one of three principal investigators of the trial.

The 300-patient trial is unique in that the multi-disciplinary teams of stroke neurology, neurosurgery and neuro-critical care physicians are participating at a minimum of 15 trial sites.

“We are seeing encouraging results with our patients and added economic benefit to our hospital,” said Gustavo Pradilla, MD, chief of neurosurgery service at Marcus Stroke & Neuroscience Center, Grady Health Systym. He is also an assistant professor of neurosurgery at Emory School of Medicine and the principal investigator of the ENRICH trial. “This trial will help

us determine in a scientifically valid manner if a precise surgical technique to avoid additional injury to the brain and early evacuation of blood contributes to improved clinical and functional outcomes."

Hemorrhagic stroke impacts more than 160,000 people in the U.S. and 3.4 million people worldwide. It is the deadliest, costliest and most debilitating form of stroke, resulting from a weakened vessel that ruptures and bleeds into the surrounding brain. It has an early mortality rate of 32 to 50 percent.

The current standard of care for hemorrhagic stroke calls for medical management of the patient, or a "watch and see" protocol that often allows the blood to remain in the brain. The ENRICH trial's goal is to compare the efficacy and safety of standard medical management of ICH to early surgical evacuation (less than 24 hours) using a parafascicular (parallel to the brain's fiber tracts) and trans-suical (natural openings and folds of the brain) surgical approach that can result in maximum clot removal, durable hemostasis, and function improvement of the patient.

"We have created groundbreaking technologies used in the trial that create navigation-compatible access to the brain in a way that's never been done before," said Jim Pearson, president and CEO of NICO. "What we are most excited about is the possibility of showing functional recovery in this very deadly and costly disease state."

Jonathan Ratcliff, MD, co-principal investigator of the ENRICH trail and assistant professor of emergency medicine and neurocritical care Emory University, said the evidence has been building for a couple of years on this new standardized approach to early surgical evacuation of ICH which led to this trial.

"The idea of including multi-disciplinary teams benefit patients and study subjects enrolled in the trial by ensuring exceptional execution of the clinical trial along with delivering the highest quality care in a well-coordinated fashion," said Rafcliff. "This alone comforts a lot of families and provides a foundation of hope for a better outcome for their loved one."

For more information about the ENRICH trial and to learn more about patient criteria, visit www.ENRICHtrial.com.