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NICO Announces Hemorrhagic Stroke Trial Lead by Emory University and Grady Memorial
Randomized controlled trial to help determine best course of treatment for deadliest form of stroke

INDIANAPOLIS, January 13, 2016 — Two of Atlanta’s nationally renowned comprehensive stroke centers associated with Emory University School of Medicine have joined neurosurgical device maker NICO Corporation to perform a randomized controlled trial evaluating the clinical effectiveness of early surgical intervention using BrainPath® following spontaneous intracerebral hemorrhage (ICH), the deadliest, most costly and debilitating form of stroke. The Emory Stroke Center of Emory University hospitals and the Marcus Stroke & Neuroscience Center of Grady Memorial Hospital will lead the trial, ultimately comparing the outcomes between early intervention using atraumatic access with BrainPath for fluid evacuation and a medically managed cohort.

This trial will build on [current peer-reviewed clinical data on the BrainPath Approach](#) including the [results](#)¹ of a multi-center pilot study presented at the 2015 International Stroke Conference. The study was on the safety and efficacy of hematoma evacuation using a trans-sulcal surgical approach with BrainPath and showed “statistically significant” improvement in patients’ neurological state associated with early intervention. This improvement was reported in 35 patients at 10 centers with outcomes showing 89 percent clot evacuation and no new surgical deficits or deaths and was cited as a breakthrough in the treatment of hemorrhagic stroke by the National Stroke Association.

“This randomized trial will allow us to produce prospective data documenting the best course of action for patients we treat with this very deadly form of stroke,” said Dan Barrow, chairman of neurosurgery, Emory University. “It underlines our commitment to partnering with other institutions in establishing a standardized minimally invasive approach and contributing to establishing a new standard of care for ICH patients.”

Hemorrhagic stroke results from a weakened vessel that ruptures and bleeds into the surrounding brain. It is considered the deadliest class of stroke because blood that accumulates within the brain after the rupture is toxic, resulting in an early mortality rate of 32-50 percent². Studies show that early removal of the blood can potentially mitigate brain injury.³ However, the current standard of care calls for medical management of the patient or a “watch and see” protocol that often allows blood to remain in the brain⁴.

The [BrainPath device is used to access the hemorrhage site](#) by navigating through the delicate folds and fiber tracks of the brain, displacing brain tissue as it creates a corridor to the hemorrhage site and evacuate the clot, all through an opening the size of a dime. More than 300 neurosurgeons, residents and fellows have been trained on BrainPath and more than 2,500 BrainPath procedures have been completed at over 60 institutions throughout the United States since the device became commercially available three years ago.

“I have performed over 50 procedures using the BrainPath to access these bleeds,” said Gustavo Pradilla, MD, chief of neurosurgery, Grady Memorial Hospital. “My early experience is encouraging and I am hopeful the results of this trial, in addition to the growing body of clinical evidence, will provide a new standard for better outcomes for these patients.”

The trial will include up to 10 centers and will begin in 2016 with approximately one year for patient enrollment and 6 months of patient follow up. Ideal trial candidates are spontaneous supratentorial ICH patients with a good clinical chance of benefiting from the surgical treatment based on well-defined criteria for study enrollment.

“It is encouraging that recent ischemic stroke trials have shown clinical success with mechanical technology for the removal of clots. We want to provide the same level of research and validation for treatment protocols for our ICH patients,” said Michael Frankel, chief of neurology, Grady Memorial Hospital, and professor of neurology at Emory. “This study could contribute to revolutionizing the standard of care for this high-risk patient population.”

Learn more about the NICO BrainPath and its use for accessing hemorrhagic stroke by visiting the website at www.NICOneuro.com. Procedure videos showing atraumatic access with BrainPath can be found on YouTube at NICOneuroCorp.

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¹Labib M, et al. The safety and efficacy of image-guided trans-sulcal radial corridors for hematoma evacuation: a multicenter study. Late breaking oral presentation LB12 at: 2015 International Stroke Conference; February 11-13, 2015; Nashville, TN.

² Adeoye, O. & Broderick, J.P. *Nat. Rev. Neurol.* 6, 593-601 (2010); published online 28 September 2010; doi:10.1038/nrneurol.2010.146.

³Zhou, et al. Minimally Invasive Surgery for Spontaneous Supratentorial Intracerebral Hemorrhage: A meta-Analysis of Randomized Controlled Trials. *Stroke*. 2012; 43:2923-2930; September 18, 2012.

⁴Tariq, et al. New Guidelines for Spontaneous Intracranial Hemorrhage: A Roadmap for Optimizing Outcomes. *Neurosurgery*. 2015 Oct;77(4):N10-11.