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Contact: Elizabeth Dowling
212-523-4047

Clinical Trial Launched To Evaluate the Safety and Efficacy of New Device To Treat Brain Aneurysms

Hyman-Newman Institute for Neurology and Neurosurgery at Roosevelt Hospital to Participate

Flow Re-Direction Endoluminal Device (FRED) May Offer Hope for Wide-Neck Brain Aneurysms Previously Considered Untreatable

New York, NY (November 5, 2013) An estimated six million people in the United States have an unruptured brain aneurysm, a bulge or sac that develops in an artery because the wall of the vessel is weak. As the aneurysm grows, the vessel wall continues to thin and can weaken to the point that it leaks or ruptures, causing bleeding into the space around the brain. Ruptured brain aneurysms require immediate treatment and are often fatal or associated with permanent neurological disability.

Large or wide-necked aneurysms are particularly complicated to treat. But an innovative, integrated, dual-layer flow diversion stent is now being studied and may offer hope to wide-necked aneurysm patients.

If surgical intervention for an aneurysm is indicated, there have traditionally been two distinct treatment options to preserve the normal blood flow within the parent artery while completely occluding flow into the aneurysm itself: an open surgical procedure that involves the use of clips to block the aneurysm, or an endovascular approach that involves placing multiple surgical coils into the aneurysm through a micro-catheter that is passed through the body and into the brain under x-ray guidance.

Doctors at the Hyman-Newman Institute for Neurology and Neurosurgery at Roosevelt Hospital are participating in a multi-center, prospective, pivotal U.S. clinical trial to evaluate the safety and efficacy of the Microvention Inc. FRED™ flow diversion system (FRED™ -Flow Re-Direction Endoluminal Device) for the treatment of wide-necked intracranial aneurysms. The FRED™ device is a small, metallic mesh tube that is inserted into the blood vessel across the entrance to the aneurysm. The device contains the flow of blood within the tube to keep it away from the aneurysm, thereby causing the aneurysm to clot and minimizing the chance of rupture. Microvention Inc. is the creator of the device and the sponsor of the trial.
“The FRED™ system was designed to treat aneurysms that were previously thought to be untouchable,” says Johanna Fifi, MD, Director of Endovascular Stroke at the Hyman-Newman Institute for Neurology and Neurosurgery and study investigator at Roosevelt Hospital in Manhattan. “Unlike first generation flow diversion devices, The FRED™ system can be partially deployed, retrieved and accurately repositioned or redeployed to ensure the most precise placement, which we expect will result in improved outcomes for our patients.”

About the FRED™ System:
FRED is a uniquely paired and integrated dual-layer stent (essentially, a stent-within-a-stent) which is simultaneously deployed by a single operator through a micro-catheter. The higher radial force outer stent and the low porosity/high metal inner stent unite to provide ease of use, enhanced stent opening and fluoroscopic visibility, which helps reduce and redirect blood flow into the aneurysm sac.

About the Procedure:
The procedure is performed by an interventional neuroradiologist while the patient is under general anesthesia. First, an angiogram is performed by injecting a contrast dye into the target artery via a catheter inserted through an incision in the groin. This imaging allows the physician to pinpoint the precise location where the flow-redirecting stent should be placed. Under x-ray guidance, the interventional neuroradiologist positions the guide cathether, holding the device next to the opening of the aneurysm.

The FRED™ device is carefully released by removing the catheter. As the device is released, it expands to fit the wall of the artery. Contrast dye is injected once again to ensure that the FRED™ system is properly positioned. When placement of the device is complete, the catheter is removed. Study participants are asked to take blood thinning medications for up to seven days before being admitted to the hospital for the procedure and remain on these medications for six or more months after the procedure. Study participants are evaluated upon discharge and at visits scheduled one month, six months and 12 months after surgery.

Patient Eligibility:
The trial will be conducted with patients who are between 22 years and 75 years old and who have a single target intracranial aneurysm located along the internal carotid artery. The target aneurysm must have a neck ≥ 4mm or no discernable neck AND a size (maximum fundus diameter) ≥ 10mm. The parent artery diameter must be 2.5-5.0mm distal/proximal to the target intracranial aneurysm. The FRED™ system is not appropriate for patients who are contraindicated to receive anticoagulant, antiplatelet or thrombolytic drugs; have a known hypersensitivity to metals; in whom angiography demonstrates anatomy that does not permit passage or proper deployment of the device; or those with an active bacterial infection or who have a pre-existing stent in place in the parent artery of the target aneurysm.

A more detailed description of this clinical trial can be found at [http://clinicaltrials.gov](http://clinicaltrials.gov); Study Number: NCT01801007, as required by U.S. Law.

If you are interested in speaking with Dr. Fifi and a study participant, please contact Elizabeth Dowling in Roosevelt Hospital’s public affairs office at: 212-523-4047

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