PRESS RELEASE

University at Buffalo Neurosurgery

UBNS.COM

Teaching. Healing. Leading the Way.

For Immediate Release

Clinical Trial Testing New Multiple Sclerosis Treatment to Launch in Buffalo

Researchers at the University at Buffalo, led by the Department of Neurosurgery, will embark on a landmark prospective randomized double-blinded study to test the safety and efficacy of interventional endovascular therapy—dubbed "liberation treatment"—on MS symptoms and progression.

June 28, 2010 -- Recently, chronic cerebrospinal venous insufficiency (CCSVI) has been strongly associated with multiple sclerosis (MS). In a series of original studies, Dr. Paolo Zamboni of the University of Ferrara, Italy demonstrated blockage of major venous outflow from the brain and spinal cord in patients with MS. Researchers from many institutions, including the University at Buffalo, have confirmed the association.

It is hypothesized that the narrowing in the large veins in the neck and chest might cause improper drainage of blood from the brain, resulting in eventual injury to brain tissue. It is thought that angioplasty—a treatment commonly used by cardiologists and other endovascular surgeons to treat atherosclerosis—may remedy the blockages. Dr. Zamboni has further conducted preliminary studies suggesting the efficacy of venous angioplasty ("liberation procedure") in the amelioration of MS symptoms.

Now, researchers at the University of Buffalo will launch PREMiSe (Prospective Randomized Endovascular therapy in Multiple Sclerosis) to determine if endovascular intervention via balloon angioplasty to correct the blockages improves MS symptoms or progression. PREMiSe is believed to be the first IRB-approved prospective randomized double-blinded study of balloon angioplasty for MS being performed in a rigorous fashion in the US with significant safeguards in place to ensure careful determination of risks and benefits.

The study is being led by principal investigator Dr. Adnan Siddiqui along with co-principal investigators Dr. Elad Levy and Dr. L.N. Hopkins of the University at Buffalo Department of Neurosurgery. Additional independent researchers from University at Buffalo will participate in the evaluation and follow-up of study patients. An independent Data Safety Monitoring Board (DSMB) will ensure the safety and effectiveness of the study on an ongoing basis.

In the first phase of the study, ten MS patients from the United States and Canada exhibiting venous insufficiency will undergo minimally invasive venous angioplasties to determine if the procedure can be performed safely. The procedures, scheduled for June 29 and 30, 2010, will be performed by Drs. Siddiqui and Levy at Kaleida Health's Millard Fillmore Gates Hospital in Buffalo, New York.

The second phase of the study will randomize 20 MS patients to undergo either venous angioplasty or a "sham angioplasty" (i.e. a catheter will be inserted but there will be no inflation of the balloon). The treatment will be blinded in such a way that neither the patient undergoing the procedure nor the clinicians evaluating the patient will be aware which procedure was performed.

If results suggest an appropriate safety profile and preliminary effectiveness, then researchers will approach the University at Buffalo Institutional Review Board (IRB) for an extension of the protocol to study a larger number of patients in order to convincingly prove or disprove a causal relationship between CCSVI and MS.

Multiple sclerosis is estimated to affect more than 400,000 people in the United States and over 2 million people worldwide. It is typically a disease of young adults characterized by either a relapsing or progressive decline in neurologic function with resultant significant disability. It is an inflammatory neurological disease widely considered to be autoimmune in nature, though its exact origins remain elusive.

If angioplasty is proven effective at improving MS symptoms, the resultant implications for the future of MS treatment could be monumental. The physicians conducting PREMiSe are cautious but optimistic that initial findings will be promising.

About UBNS

University at Buffalo Neurosurgery (UBNS) is an academic neurosurgical group and leading regional referral center for cerebrovascular disorders run by a distinguished team of neurosurgical specialists and subspecialists committed to superior patient care, resident education, and translational research. UBNS diagnoses and treats a wide range of conditions, including but not limited to aneurysms; stroke; back and neck pain; epilepsy; Parkinson's disease; hydrocephalus; and tumors of the brain, spine, and skull base. It is also the only neurosurgical group in Western New York with FDA approval to conduct device-related clinical trials for acute stroke.

About UB

The University at Buffalo (UB) is a premier research-intensive public university, a flagship institution in the State University of New York system, and its largest and most comprehensive campus. UB's more than 28,000 students pursue their academic interests through more than 300 undergraduate, graduate, and professional degree programs. Founded in 1846, the University at Buffalo is a member of the Association of American Universities.

Contact: Caitlin Hartney / University at Buffalo Neurosurgery / chartney@ubns.com / 716.887.5200