University at Buffalo launches clinical trial of new multiple sclerosis treatment

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Buffalo medical researchers led by a team from the University at Buffalo 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 the symptoms and progression of Multiple Sclerosis (MS).

Recent research has strongly associated chronic cerebrospinal venous insufficiency (CCSVI) with MS.

In a series of original studies, Paolo Zamboni MD, of the University of Ferrara, Italy, found 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 -- treatment commonly used by cardiologists and other endovascular surgeons to treat atherosclerosis -- may remedy the blockages.

Zamboni has conducted preliminary studies that suggest the efficacy of venous angioplasty - "liberation procedure" -- in the amelioration of MS symptoms.

Now, researchers at the University at Buffalo will launch PREMiSe

(Prospective Randomized Endovascular therapy in Multiple Sclerosis), a study to determine if endovascular intervention via balloon angioplasty to correct the blockages improves MS symptoms or progression.

PREMiSe is believed to be the first prospective randomized double-blinded study of balloon angioplasty for MS being performed with Institutional Review Board approval in a rigorous fashion in the US with significant safeguards in place to ensure careful determination of risks and benefits.

The study is led by principal investigator Adnan Siddiqui, MD, assistant professor of Neurosurgery, UB School of Medicine and Biomedical Sciences, with co-principal investigators Elad Levy, MD, associate professor, and L.N. Hopkins, MD, professor and chair of the UB 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 who exhibit venous insufficiency will undergo minimally invasive venous angioplasties to determine if the procedure can be performed safely. The procedures began June 29 and will continue today (June 30), performed by Siddiqui and Levy at Kaleida Health's Millard Fillmore Gates Hospital in Buffalo, New York.

In its second phase, the study will randomize 20 MS patients who will 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, researchers will approach the University at Buffalo 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 more than two million people worldwide. It is typically a disease of young adults characterized by either a relapsing or progressive decline in neurologic function resulting in 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 implications for the future of MS treatment could be monumental. The physicians conducting PREMiSe are cautious but optimistic that initial findings will be promising.

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.

Provided by University at Buffalo