BNAC

Buffalo Neuroimaging Analysis Center

March 12, 2010

CCSVI Diagnostic Procedure Update

Dear BNAC CCSVI study enrollee:

Please forgive the impersonal nature of this email which is being shared with several hundred individuals already enrolled or currently being enrolled in a previously announced program. This program was designed to provide a diagnostic procedure for chronic cerebrospinal venous insufficiency (CCSVI) for individuals with a diagnosis of multiple sclerosis.

Upon the review and advice of the Institutional Review Board (IRB) at the State University at Buffalo, BNAC has modified the program's design for the CCSVI open-label study of the prevalence (frequency) and clinical, MRI and genetic correlates of CCSVI in adult and pediatric patients with clinically definite and possible MS. The study is designed to investigate the relationship between venous insufficiency and MS, documenting the status of cerebro-spinal venous flow, the status of lesions and the presence of iron deposits and clinical and genetic correlates in participating patients.

The purpose of the program modification was to ensure that individual study results were not proffered by BNAC as a diagnosis for which any treatment is implied or advised.

Review and approval of the proposed revised study design is expected to be complete in April 2010 and at that time participants will be advised of the details and invited to participate.

Pending approval by the IRB, BNAC will open enrollment for individuals with confirmed or possible MS. At that time, details on eligibility and enrollment procedures will be announced on the BNAC website, www.bnac.net. However, study procedures will still include MRI and Doppler of the brain and neck, a clinical examination with a neurologist, neuropsychological testing and blood draw for genetic testing.

Individuals enrolled in the previously announced diagnostic procedure will be given priority option to participate in this study and, upon IRB approval of the study design, will be contacted individually. There is no need to email or call BNAC at this time.

This will be an open-label research study, which means no investigators or patients will be blinded to the study results. Analysts, however, will be blinded to the results to ensure objective analysis. While results will be shared with individual participants consistent with our ethical obligations, results will not constitute a diagnosis or dictate any specific treatment for MS, which should remain between you and your physician.

Study procedures will include MRI and Doppler of the brain and neck, a clinical examination with a neurologist, neuropsychological testing and blood draw for genetic testing.

At this time, no funds are available to support the study. Therefore, it will be funded primarily through fees paid by study participants. The per-participant cost of $4,500 USD will cover study design and implementation as well as the above-referenced procedures. There will be no financial compensation for participation, travel, or related expenses.

Consistent with BNAC practice, study results will be peer reviewed and published.

We thank you for your interest and attention to this important notice. Prior to your participation in the study we will request that you acknowledge receipt of this notice and your understanding of the change described above.

We will be in touch again in April to advise you of the results of our IRB application and of the next steps in the process.

Thank you again for your continuing interest.

Robert Zivadinov, MD, Ph.D

Director

Buffalo Neuroimaging Analysis Center