



May 17, 2011

FDA and IRB Approved Clinical Trial of Venous Sinus Stenting in patients with refractory Idiopathic Intracranial Hypertension

Dear Esteemed Colleague:

We are pleased to announce the availability of a new clinical trial at our institution that aims to evaluate the safety and efficacy of **venous sinus stenting in patients with refractory Idiopathic Intracranial Hypertension (IIH) and significant venous sinus stenosis**. This clinical trial, a joint effort between the Departments of Neurological Surgery, Neurology and Neuroscience, and Ophthalmology at Weill Cornell Medical College and New York-Presbyterian/Weill Cornell Medical Center, will potentially provide patients who have not responded well to available treatments a new therapy to help control their symptoms and preserve their vision. It is our hope that in a select set of these patients who are shown to have venous sinus stenosis, increased intracranial pressure and associated symptoms will improve after treatment.

Details regarding this IRB and FDA approved trial are included on the back of this letter. We invite you to review the criteria and hope you find this information meaningful to your practice. If you have a patient who you think may be a candidate for the clinical trial, please contact Dr. Athos Patsalides and/or Dr. Marc Dinkin.

Sincerely yours,

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Venous sinus stenting in patients with refractory Idiopathic Intracranial Hypertension (IIH)

There are many patients with **Idiopathic Intracranial Hypertension (IIH)** who do not respond to available treatments or experience medication-related side effects that affect their quality of life. Existing surgical treatments pose risks of side effects or treatment failure in some patients. At the departments of Neurological Surgery, Neurology and Neuroscience, and Ophthalmology at Weill Cornell Medical College, we are dedicated to seeking new therapies to help patients with **IIH** control their symptoms and preserve vision.

A new clinical trial at our institution aims to evaluate the safety and efficacy of venous sinus stenting in patients with refractory **IIH** and significant venous sinus stenosis. Reports published in the last few years provide pilot/preliminary data supporting the safety and efficacy of venous sinus stenting in select patients, suggesting that this technique is promising and could represent a viable alternative for refractory **IIH** patients with venous sinus stenosis. However, these studies were performed with a variety of methodologies, inclusion/exclusion criteria and primary and secondary objectives. The purpose of our study is to evaluate the safety and efficacy of this procedure in a controlled fashion, using strict inclusion and exclusion criteria, and long-term clinical and imaging follow-up.

Our trial has been approved by the Food and Drug Administration (FDA) and the Institutional Review Board (IRB) at Weill Cornell Medical College, and is now open for patient enrollment.

The major eligibility criteria are:

- Diagnosis of **IIH**
- Significant loss of visual function
- Failure of medical therapy and
- Venous sinus stenosis on MR Venography (MRV) or CT Venography (CTV).

The trial staff will review additional criteria to determine eligibility. Qualified participants will be treated with stent placement in the venous sinus to alleviate the stenosis. The follow-up period is 24 months and all participants will receive neurological and ophthalmological examinations, lumbar puncture and MRV/CTV. All will undergo close neuro-ophthalmological observation including funduscopy and visual fields. There will be no compensation for participation.

At any time, we will be available to discuss the progress of any of your patients who participate. Updates regarding the results of this treatment will be provided to you after each follow-up visit and at the end of the study. At the conclusion of the study, the patient will be referred back to you as their personal physician.