Synergy Health Concepts, Inc.
IRB Protocol: Venous Obstruction in Neurodegenerative Disorders Research Registry
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Study Abstract

Subjects will be screened initially using established inclusion and exclusion criteria. Subjects that meet eligibility requirements will be provided with patient education material and an informed consent for review. Once all questions have been answered by the primary investigator or sub-investigators, the subject will voluntarily sign the informed consent. A patient questionnaire will be completed pre-procedure. The subject will have a Haacke MRV, a consultation with the physician, venography with possible angioplasty and/or stent placement. The subject will be required to complete the patient questionnaire at 6 and 12 months post-procedure. In addition, the subject will be required to obtain a Zamboni protocol Doppler study at 6 months and a Haacke MRV at 12 months. The risks and benefits of the research registry and procedure are outlined in the informed consent. Steps are taken during the intake process to minimize risks by thoroughly assessing the subjects for co-morbidities that may increase risk. After review of all intake data, the investigator and subject will determine if the subject is an appropriate candidate.

Statement of Purpose and Background

Studies indicate that a phenomenon called CCSVI (chronic cerebrospinal venous insufficiency), an abnormality in blood drainage from the brain and spinal cord, may contribute to neurodegenerative disorders. This hypothesis has been put forth by Dr. Paolo Zamboni and is now being pursued by other investigators as well. Dr. Zamboni and others state that this pilot study warrants a subsequent larger and better controlled study to definitively evaluate the possible impact of CCSVI on the disease process in MS. There is other data that suggests the contrary. This amplifies the need for additional studies that can quickly provide answers regarding CCSVI treatment efficacy. Many questions remain about how and when CCSVI might play a role in nervous system damage and whether venous angioplasty is helpful in treating the symptoms of CCSVI. This research registry will provide data that will allow researchers to classify abnormal valve and venous morphology, distinguish vessels which are more responsive to treatment, determine groups who respond more favorably to treatment, and overall evaluate the outcomes of venous angioplasty in various neurodegenerative disorders that involve venous

obstruction.

Subjects

Human subjects will be approached for participation in this registry that are receiving or seeking medical care at Synergy Health Concepts, Inc. No individuals shall be excluded from participation in the Research Registry based on race, ethnicity, or gender.

Selection Criteria for Research Registry will be assessed by the Study Intake Coordinator using the Venous Obstruction in Neurodegenerative Diseases Research Registry Intake Form:

Inclusion Criteria:

a. Ability to comprehend the nature of the study, including the risks and benefits and execute an informed consent
b. Males or Females between the ages of 20 and 60 years of age.
c. Voluntary agreement to participate in the Venous Obstructions in Neurodegenerative Diseases Research Registry.

Exclusion Criteria:

a. Any implantable/metallic objects that prevents subject from having a magnetic resonance imaging (MRI/MRV) study.
b. History of uncontrolled hypertension
c. Previous CCSVI treatment
d. Presence of hypercoagulable state
e. Special Populations. Special groups include, but are not limited to children, prisoners, pregnant women, fetuses, and cognitively impaired individuals who are unable to provide informed consent.

Recruitment Methods

All subjects will voluntarily approach the center for treatment independently without the use of recruitment measures.

Informed Consent Process

Once a patient contacts the center voluntarily, the research intake coordinator will interview the patient for eligibility. If the patient meets eligibility requirements, written information regarding the Research Registry will be sent to the patient for

review. If the patient voluntarily wishes to proceed, the scheduler will schedule the patient for Haacke MRV, consult with investigator/physician, venography procedure and follow up consult. The research intake coordinator will obtain medical history. During the consultation appointment, the investigator will discuss participation in the registry; including the purpose of the study, risks, benefits, confidentiality, investigator's telephone number to call for questions, etc. The patient will have ample opportunity and time to ask questions and have them answered by the investigator. If the patient chooses to participate, the informed consent will be executed by the patient and witnessed by the research intake coordinator.

Study Location

Consult/Patient Visit locations include:
Synergy Health Concepts, Inc.
1640 Newport Blvd., Suite 310, Costa Mesa, CA 92627

Procedure locations include:

Renaissance Surgical Arts at Newport Harbor
1640 Newport Blvd., Costa Mesa CA 92627

Fountain Valley Hospital
17100 Euclid Street, Fountain Valley, CA 92708

Diagnostic imaging locations include:

Newport Diagnostic Center
1605 Avocado Avenue, Newport Beach, California 92660

Pacific Breast Care
1640 Newport Blvd # 210, Costa Mesa, California 92627

Research Design and Methods

Synergy Health Concepts, Inc. is requesting participation in a Research Registry. By placing the medical record information of many patients in to a research registry, researchers will have the ability to conduct research studies directed at increasing our knowledge regarding venous obstruction in neurodegenerative disorders and the efficacy of venous angioplasty.

The subjects will be requested to complete a patient questionnaire that is located at www.synergyhealthconcepts.com on three (3) separate occasions; pre-treatment,

six (6) months post-treatment and twelve (12) months post-treatment. The questionnaire should take approximately thirty (30) minutes to complete. The subject will undergo venography and possible venous angioplasty with possible stent placement. This procedure takes approximately one (1) hour with a two to three hours recovery period. In addition, the subject will be requested to have a Haacke MRV pre-treatment, a CCSVI protocol Doppler study six (6) months post-treatment and a Haacke MRV twelve (12) months post-treatment. Each of these studies is approximately two (2) hours in length.

Potential Benefits.

You may receive relief from some of your symptoms associated with venous obstruction. However, you may not experience any relief from your symptoms and possibly even be worse after the procedure. Your medical record information contained within the Research Registry will be used for research studies directed at improving our knowledge and treatment of Venous Obstructions in Neurodegenerative Disorders and this knowledge may benefit patients with this disease in the future.

Potential Risks.

Risks Associated with Venography and/or Venous Angioplasty include:

- Recurrence of your symptoms or restenosis within your vein
- Complications from sedation including aspiration
- Bleeding at the needle site
- Allergic reaction to dye (contrast)
- Injury to a vein resulting in bleeding
- Blood clot formation within the vein
- Misplacement or displacement of venous stents
- The use of thrombolysis to dissolve and remove blood clots, which in itself has risks including bleeding and stroke.
- Potential worsening of your condition
- Heart arrhythmias or heart attack
- Stroke
- Death

Risks Associated With Magnetic Resonance Imaging (MRI)

- If you have metal fragments or implantable devices, the MRI could dislodge this item which may lead to life-threatening complications.

- Claustrophobia
- Contrast Reaction

Management of Risk

Precautions are incorporated into the research activity to reduce or limit the severity, duration and likelihood of harm. All subjects are screened thoroughly to ensure the subject does not have co-morbidities that may increase the risk of harm.

Confidentiality

All patient medical record information is stored electronically according to state and federal regulations. In addition, all data is password protected and only research personnel that are involved in this research registry have access to the data. Synergy Health Concepts, Inc. does not disclose personally identifiable data to anyone other than the research team without the written consent of the subjects or their legal representative. (Exceptions may be made in case of emergency need for intervention or as required by regulatory agencies). Please see SYNERGY HEALTH CONCEPTS, INC. HIPAA AUTHORIZATION TO USE HEALTH INFORMATION FOR RESEARCH.

Costs

There will be charges for any testing and for the venography. Your insurance may or may not cover the cost of the test of treatment. Synergy Health Concepts, Inc. will submit claims as a courtesy.

Compensation and Incentives

There is no compensation for participating in this Research Registry.

Treatment for Possible Physical Injury Resulting From Research Procedures

In the event a subject suffers any complication or physical injury, medical treatment will not be provided free of charge. Subjects are instructed to notify the principal investigator as soon as the injury occurs so that appropriate treatment can be rendered and notification to the IRB can take place.

Investigator(s) Qualifications

Copies of the curriculum vitae and credentials are on file with Biomed IRB.