# Evaluation of the Safety and Effectiveness of the CereVasc® eShunt® System in Normal Pressure Hydrocephalus

**Status:** RECRUITING

## Eligibility Criteria

**Age:** 60 years and over

This study is NOT accepting healthy

**Healthy Volunteers:** volunteers

**Inclusion Criteria:**

Each subject must meet the following criteria: 1. Patients ≥60 years old on the day of study informed consent 2. Patient or legally authorized representative is able and willing to provide written informed consent 3. History or evidence of gait impairment with a duration ≥3 months 4. Clinical presentation consistent with NPH including two or more of the clinical triad (i.e., history of gait disturbance, progressive mental deterioration, and urinary urgency or incontinence), together with all of the following: 1. Brain MRI signs of ventricular enlargement disproportionate to cerebral atrophy (Evans' Index \>0.3) and the absence of severe hippocampal atrophy, 2. Pre-procedure spinal tap test or lumbar drain with subsequent gait disturbance improvement (Timed Up and Go Test) of at least 20%, 3. CSF opening pressure ≥8 cmH2O, 4. Baseline cognitive evaluation assessed by Montreal Cognitive Assessment (MoCA) test score ≥12 5. Patient is willing and able to attend all scheduled visits and comply with study procedures. 6. Confirmation of anatomy suitable for the eShunt procedure, as determined by evaluation of pre-procedure imaging (CT and MRI) and approved by an independent anatomical screening committee.

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**Exclusion Criteria:**

Each subject may not: 1. Be unable to walk 10 meters (33 feet) with or without an assistive device 2. Be diagnosed with obstructive hydrocephalus 3. Have an active systemic infection or infection detected in CSF 4. Have had prior or existing shunts, endoscopic third ventriculostomy, or any previous surgical intervention for hydrocephalus 5. Demonstrate hypersensitivity or contraindication to heparin or radiographic contrast agents against which the subject cannot be adequately pre-medicated, desensitized or where no alternative is available 6. Have occlusion or stenosis of the internal jugular vein which would prohibit access to the IPS 7. Present with venous distension in the neck on physical exam 8. Have medical conditions associated with prolonged elevation of jugular venous pressure, including jugular vein stenosis or stricture, right sided heart failure, cirrhosis of the liver, arteriovenous fistulas in the arm for dialysis purposes, or an arterial venous fistula or malformation in the neck or brain 9. Have history of bleeding diatheses, coagulopathy or refuse to consent for blood transfusion in cases of emergency 10. Have had an ischemic stroke or transient ischemic attack within 180 days of eShunt procedure 11. Have documented evidence of a deep vein thrombosis superior to the popliteal vein 12. Have intrinsic blood clotting disorder 13. Have medical conditions requiring anticoagulation which is unable to be managed to allow for surgical procedure 14. Have presence of a posterior fossa tumor or mass 15. Have a life expectancy \<1 year 16. Be currently participating in another interventional (drug, device, etc.) research project that may confound the results of this study. 17. Have established diagnosis of neurodegenerative diseases such as Parkinson's disease, Alzheimer's disease, or Lewy body dementia 18. Be diagnosed with schizophrenia or any psychiatric diagnosis (including depression) that may complicate outcome evaluation 19. Need an intracranial neurosurgical procedure within 180 days of study index procedure 20. Be unwilling or unable to comply with follow-up requirements 21. Have mRS of 0, 5, or 6

## Conditions & Interventions

**Interventions:**
DEVICE: CereVasc eShunt System, DEVICE: VP Shunt
**Conditions:**
Normal Pressure Hydrocephalus

## More Information

**Contact(s):** Ona Whelove - clinicaltrials@cerevasc.com
**Principal Investigator:**
**Phase:** NA
**IRB**
**Number:**
**System ID:** NCT06498960

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