Assessment of CSF Shunt Flow During Activities of Daily Living and Sleep With a Thermal Measurement Device

Status: RECRUITING

Eligibility Criteria

Age: 2 years to 21 years old

This study is NOT accepting healthy

Healthy Volunteers: volunteers

Inclusion Criteria:

1. Existing ventricular CSF shunt 2. (Cohort A) A history of stable ventricular size, no shunt revision in the previous 2 years, and no current symptoms of shunt failure 3. (Cohort B) A shunt revision in the previous 7 days and the investigator judges that the patient will likely be discharged within 4 days of the enrollment date 4. Region of intact skin overlying an unambiguously identifiable palpable chronically indwelling ventricular shunt which crosses the clavicle and is appropriate in size for application of the study device 5. Signed informed consent by subject or a parent, legal guardian, health care agent, or surrogate decision maker (according to local statutes) 6. Subject is at least 5 years old but \< 22 years old

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Exclusion Criteria:

1. Shunt is not palpable or depth of shunt where the device will be placed is greater than 4 mm per ultrasound evaluation 2. Presence of an interfering open wound or edema in the study device measurement region 3. Subject-reported history of serious adverse skin reactions to silicone-based adhesives 4. Investigator judges that the subject is likely to be lost to follow-up due to unavailability or clinical outcome being unobtainable 5. Investigator judges that the subject is unlikely to successfully take reliable measurements at home 6. Investigator judges that the subject/subject's caretaker would not be able to successfully place the device without assistance 7. Use of the study device would interfere with standard patient care, or emergency surgery that cannot be delayed, or participation in the study will interfere with, or be detrimental to, administration of optimal healthcare to the subject 8. Prior enrollment in this study 9. Participation in any other investigational procedural, pharmaceutical, and/or device study that may influence the collection of valid data under this study

Conditions & Interventions

Interventions:
DEVICE: wireless thermal anisotropy measurement device
Conditions:
Hydrocephalus

More Information

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