

HCRN Endoscopic Versus Shunt Treatment of Hydrocephalus in Infants

Status: RECRUITING

Eligibility Criteria

Age: 1 day to 104 weeks old

This study is NOT accepting healthy

Healthy Volunteers: volunteers

Inclusion Criteria:

1. Corrected age \leq 104 weeks and 0 days, AND 2. Child is \geq 37 weeks post menstrual age, AND 3. Child must have symptomatic hydrocephalus, defined as: Ventriculomegaly on MRI (frontal-occipital horn ratio (FOR) >0.45 , which approximates "moderate ventriculomegaly"), and at least one of the following: * Head circumference >98 th percentile for corrected age with either bulging fontanelle or splayed sutures * Upgaze paresis/palsy (sundowning) * CSF leak * Papilledema * Tense pseudomeningocele or tense fluid along a track * Vomiting or irritability, with no other attributable cause * Bradycardias or apneas, with no other attributable cause * Intracranial pressure (ICP) monitoring showing persistent elevation of pressure with or without plateau waves AND 4. No prior history of shunt insertion or endoscopic third ventriculostomy (ETV) procedure (previous temporization devices and/or external ventricular drains permissible)

Exclusion Criteria:

1. Hydrocephalus due to intraventricular hemorrhage in a child born before 37 weeks gestational age; OR 2. Anatomy not suitable for ETV+CPC or anteriorly placed ventriculoperitoneal shunt defined as: * Moderate to severe prepontine adhesions on steady state free precession (SSFP) or T2 weighted fast (turbo) spin echo (FSE/TSE) MRI, which includes the following sequences: FIESTA, FIESTA-C, TrueFISP, CISS, Balanced FFE (bFFE), CUBE, SPACE, VISTA, IsoFSE, and 3D MVOX * Closure of one or both foramina of Monro * Thick floor of third ventricle (≥ 3 mm) * Narrow third ventricle (<5 mm) * Presence of scalp, bone, or ventricular lesions that make placement of an anterior shunt impracticable; OR 3. Underlying condition with a high chance of mortality within 12 months; OR 4. Hydrocephalus with loculated CSF compartments; OR 5. Peritoneal cavity not suitable for distal shunt placement; OR 6. Active CSF infection; OR 7. Hydranencephaly; OR 8. Child requires an intraventricular procedure (e.g. endoscopic biopsy) in addition to the initial first-time permanent procedure for the treatment of hydrocephalus.

Conditions & Interventions

Interventions:

PROCEDURE: Endoscopic Third Ventriculostomy with Choroid Plexus Cauterization (ETV+CPC), DEVICE: Ventriculoperitoneal Shunt

Conditions:

Hydrocephalus

Keywords:

Hydrocephalus, Infants, Ventriculoperitoneal Shunt, ETV+CPC, endoscopic third ventriculostomy, choroid plexus cauterization

More Information

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Principal Investigator:

Phase: PHASE3

IRB

Number:

System ID: NCT04177914

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