

Neuroendoscopic lavage for treatment of intraventricular hemorrhage (IVH) and posthemorrhage hydrocephalus (PHH) among preterm infants

Submission date 21/10/2015	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 30/11/2015	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 23/11/2015	Condition category Circulatory System	<input type="checkbox"/> Individual participant data <input type="checkbox"/> Record updated in last year

Plain English summary of protocol

Background and study aims

Posthemorrhagic hydrocephalus (PHH) is a build-up of fluid on the brain that occurs after bleeding inside the skull. The excess fluid puts pressure on the brain, which can damage it. PHH is a major problem for premature infants. Currently, most premature infants with this condition require a permanent ventriculoperitoneal (VP) shunt - a medical device that relieves the pressure on the brain. However, there is some evidence that washing away the blood with use of a long, thin, flexible tube called an endoscope will reduce the need for a shunt by resolving the build-up of fluid in the brain. The aim of this study is to find out whether washing away the blood with an endoscope reduces the need for a permanent VP shunt in premature infants with PHH.

Who can participate?

Premature infants with PHH who are eligible for a surgically implanted temporary device for draining excess cerebrospinal (brain) fluid.

What does the study involve?

All participants receive the same treatment. Eligible infants who are receiving a temporary shunt or device undergo a procedure to wash away the blood through an endoscope.

What are the possible benefits and risks of participating?

The benefit of this procedure is the possible reduction in the need for a permanent shunt. There is evidence that washing away the blood can resolve the build-up of fluid in the brain. Endoscopy at this young age can potentially increase the risk of seizures. Therefore, infants will be placed on temporary anti-seizure medications to reduce that risk.

Where is the study run from?

Bloomberg Children's Center at the Johns Hopkins Hospital (USA)

When is the study starting and how long is it expected to run for?
November 2015 to November 2018

Who is the main contact?
Dr Edward Ahn
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Contact information

Type(s)
Scientific

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Study information

Scientific Title
Neuroendoscopic lavage for treatment of intraventricular hemorrhage (IVH) and posthemorrhage hydrocephalus (PHH) among preterm infants: a single-center interventional study

Study objectives
Adding an endoscopic lavage to ventriculosubgaleal shunt or ventricular access device insertion reduces the rate of requiring a permanent ventriculoperitoneal shunt in premature infants with intraventricular hemorrhage and post-hemorrhagic hydrocephalus.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Johns Hopkins Office of Human Subjects Research Institutional Review Board, 17/09/2015,
Study Number IRB00065909

Study design
Single-center interventional study

Primary study design

Interventional

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Intraventricular hemorrhage (IVH) and posthemorrhagic hydrocephalus (PHH)

Interventions

There is only one treatment arm in this study. With parental consent, eligible infants who are receiving a temporary ventriculosubgaleal shunt or ventricular access device will also receive the endoscopic lavage procedure. The endoscopic lavage procedure will use the same access point as the ventriculosubgaleal shunt. Bloody CSF will be irrigated and proteinaceous fluids removed from the ventricles. At the end of the lavage, we will insert the ventriculosubgaleal shunt per standard routine.

Intervention Type

Procedure/Surgery

Primary outcome(s)

Rate of ventriculoperitoneal (VP) shunt insertion within 12 months of follow-up

Key secondary outcome(s)

1. Number of overall procedures
 2. Rate of infection
 3. Rate of supratentorial multiloculated hydrocephalus
- Outcomes assessed at one year after the procedure

Completion date

01/11/2018

Eligibility

Key inclusion criteria

Premature infants with intraventricular hemorrhage (IVH) and posthemorrhagic hydrocephalus (PHH) who are eligible for a ventriculosubgaleal shunt or ventricular access device

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Neonate

Sex

All

Key exclusion criteria

Patients not suitable for surgical intervention in the operating room

Date of first enrolment

01/11/2015

Date of final enrolment

01/11/2018

Locations

Countries of recruitment

United States of America

Study participating centre

Johns Hopkins Hospital

600 N. Wolfe St

Phipps 560

Baltimore

United States of America

21287

Sponsor information

Organisation

Johns Hopkins Hospital (USA)

ROR

<https://ror.org/05cb1k848>

Funder(s)

Funder type

Other

Funder Name

Investigator initiated and funded

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Available on request