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	 Prospectively registered Protocol
Registration date 30/11/2015	Overall study status Completed	Statistical analysis planResults
Last Edited 23/11/2015	Condition category Circulatory System	 Individual participant data Record updated in last year

Plain English Summary

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 eahn4@jhmi.edu

Contact information

Type(s) Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers N/A

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 hypothesis

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

Secondary study design Non randomised study

Study setting(s) Hospital

Study type(s) Treatment

Participant information sheet

Not available in web format, please use the contact details below to request a patient information sheet

Condition

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 measure

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

Secondary outcome measures

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

Overall study start date

01/11/2015

Overall study end date

01/11/2018

Eligibility

Participant 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

Age group Neonate

Sex Both

Target number of participants 18

Participant exclusion criteria Patients not suitable for surgical intervention in the operating room

Recruitment start date 01/11/2015

Recruitment end date 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)

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Sponsor type Hospital/treatment centre

ROR https://ror.org/05cb1k848

Funder(s)

Funder type Other

Funder Name Investigator initiated and funded

Results and Publications

Publication and dissemination plan To be confirmed at a later date

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary Available on request