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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

Registration date
30/11/2015

Overall study status
Completed

Last Edited
23/11/2015

Condition category
Circulatory System

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] 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?
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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 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

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

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 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

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

Age group
Neonate

Sex
Both

Target number of participants
18

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
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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