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Effects of different types of shunt in congenital hydrocephalus in terms of early drainage of cerebrospinal fluid

Submission date
09/09/2026

Recruitment status
No longer recruiting

Registration date
24/09/2026

Overall study status
Completed

Last Edited
02/10/2026

Condition category
Other

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

Plain English summary of protocol

Background and study aims
Hydrocephalus is a condition in which fluid called cerebrospinal fluid (CSF) builds up in the brain. This can increase pressure inside the head and may damage brain tissue if left untreated. One of the most common treatments is the insertion of a ventriculo-peritoneal (VP) shunt, a device that drains excess fluid from the brain into the abdomen.

VP shunts are available with different pressure settings, including low-pressure and medium-pressure valves. However, there are currently no clear guidelines on which pressure setting provides the best early drainage of fluid in children with congenital hydrocephalus. This study aimed to compare low-pressure and medium-pressure VP shunts to determine their effects on early drainage of CSF after surgery in young children with congenital hydrocephalus.

Who can participate?
Children younger than 2 years of age with congenital hydrocephalus who required their first VP shunt operation and had an open anterior fontanelle (the soft spot on the top of a baby's head).

What does the study involve?
Participants were randomly assigned to one of two groups. Children in Group A received a low-pressure VP shunt, while children in Group B received a medium-pressure VP shunt.

Researchers assessed how well CSF was drained after surgery by examining the status of the anterior fontanelle during the first five days after the operation. They also measured the ventriculo-hemispheric ratio, an imaging measure used to assess the size of the brain ventricles, before surgery and on the fifth postoperative day. The results from the two groups were then compared.

What are the possible benefits and risks of participating?
Participants may have benefited if one type of shunt provided more effective early drainage of CSF than the other. The main risks were those normally associated with VP shunt surgery and its possible complications.

Where is the study run from?
All India Institute of Medical Sciences (AIIMS), Patna, India.

When is the study starting and how long is it expected to run for?
The study enrolled its first participant in January 2022 and completed follow-up in July 2023. Recruitment took place between January 2022 and February 2023.

Who is funding the study?
All India Institute of Medical Sciences (AIIMS), Patna, India.

Who is the main contact?
Dr Sourav Jana, All India Institute of Medical Sciences, Patna, India, drsouravjana@aiimspatna.org, janasourav6393@gmail.com

Contact information

Type(s)
Scientific, Public, Principal investigator

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Additional identifiers

Study information

Scientific Title
Outcome analysis of different types of fixed pressure VP shunt on early drainage of CSF in paediatric congenital hydrocephalus

Study objectives
Primary objective(s): To assess the clinical effect of type of fixed pressure VP shunt on status of anterior fontanel in paediatric congenital hydrocephalus patients
Secondary objective(s): To assess the clinical effect of type of fixed pressure VP shunt on ventriculo-hemispheric ratio in paediatric congenital hydrocephalus patients

Ethics approval required

Ethics approval required

Ethics approval(s)
Approved 29/12/2021, Institutional Ethics Committee, AIIMS Patna (Phulwari sharif, Patna, 801507, India; +91 6122821105; iec@aiimspatna.org), ref: AIIMS/Pat/IEC/PGTh/Jan21/33

Primary study design
Interventional

Allocation
Randomized controlled trial

Masking
Blinded (masking used)

Control
Active

Assignment
Parallel

Purpose
Device feasibility, Treatment

Study type(s)

Health condition(s) or problem(s) studied
Patients of congenital hydrocephalus

Interventions
In all patients, Chhabra fixed-pressure VP shunts were used, either of low-pressure or medium-pressure valve system. VP shunt was placed as per the standard approach.
To enrol patients in each group, block randomization was done using a random sequence generated by online software and it was done by a third person who was not a part of the study. The list so generated was used to make sequentially numbered opaque sealed envelopes (SNOSE) which were kept in the office. On the day of the study, after taking informed consent about the trial, one of the parents of the patient visited the office where he or she was given the top envelop. They were allocated to either of the group (A or B) as per the envelop they received. Parents were not aware about which type of shunt to be placed. Thus consecutive 30 patients satisfying inclusion and exclusion criteria, were divided equally (15 in each) in each group as per randomization sequence. During surgery, the nursing in charge (not the part of the study) would hand over the VP shunt to operating surgeon according to the allotted group without informing the type of shunt valve system.
Clinical status of Anterior fontanelle (AF) and venticulo-hemispheric ratio (VHR) by USG cranium were recorded pre-operatively one day before surgery. As per the group, the respective shunt was placed. Patients were assessed for 5 days postoperatively. Post-surgery AF status was recorded clinically on each post-operative day till POD 5 during the morning rounds by the primary investigator and VHR was recorded on POD 5 using USG cranium.
AF status was recorded as bulged (above the level of outer table of skull), flat (at the level of skull) or depressed (level below the inner table of the skull). This was given a score (+1, 0, and -1 respectively) to convert a subjective parameter into an objective parameter. The mean of the AF

weighted score was calculated for both groups. Non-Parametric tests were used to make statistical inference as data were not normally distributed. Wilcoxon-Mann-Whitney Test was used to compare the two groups in terms of AF Weighted Score (Lesser is Better) at each of the time points. Friedman test was used to explore the change in AF Weighted Score over time within each group.
VHR was calculated as the ratio of the maximum width of the frontal horns of the lateral ventricles and the maximal internal diameter of the skull by USG.
All the data were collected using physical proforma and analysed using Jamovi. No cases were missed or had any complications during the first five days postoperatively. Parents, operating surgeon, primary investigator and data analyst were blinded during the study.

Intervention Type
Device

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Low pressure and Medium pressure Ventriculo peritoneal shunt

Primary outcome(s)
1. Early drainage of CSF measured using Anterior fontanelle (AF) status and Ventriculo hemispheric ratio (VHR) at post operative days (POD) till POD 5 for preoperative AF status and AF status on each, and POD 5 for preoperative VHR and VHR

Key secondary outcome(s)

Completion date
24/07/2023

Eligibility

Key inclusion criteria
1. Children with congenital hydrocephalus
2. Age less than 2 years
3. Anterior fontanelle open
4. First time shunt being placed

Healthy volunteers allowed
No

Age group
Mixed

Lower age limit
0 Days

Upper age limit
2 Years

Sex
All

Total final enrolment
30

Key exclusion criteria
1. Children having severe cardiac or renal anomaly
2. Children in sepsis or shock or organ failure
3. Shunt redo surgery being done
4. Hydrocephalus other than congenital origin

Date of first enrolment
04/01/2022

Date of final enrolment
06/02/2023

Locations

Countries of recruitment
India

Study participating centre
All India Institute of Medical Sciences, Patna
Phulwari Sharif
Patna, Bihar
India
801507

Sponsor information

Organisation
All India Institute of Medical Sciences, Patna

ROR
https://ror.org/033ax5g32

Funder(s)

Funder type

Funder Name
All-India Institute of Medical Sciences

Alternative Name(s)
AIIMS

Funding Body Type
Government organisation

Funding Body Subtype
Local government

Location
India

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study will be available upon request from Dr Sourav Jana (janasourav6393@gmail.com)
Masterchart of the data (in a spreadsheet) collected will be shared on request
Consent from all the participants was obtained
Anonymized data will be shared
Study was approved by Institutional Ethics Committee, AIIMS Patna. So there is no ethical restrictions to publish the data

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Basic results		02/10/2026	02/10/2026	No	No
Dataset			02/10/2026	No	No
Plain English results		02/10/2026	02/10/2026	No	Yes
Protocol file			02/10/2026	No	No
Statistical Analysis Plan			02/10/2026	No	No