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A study comparing the effectiveness of single burr hole of the skull with double burr hole of the skull in the management of chronic subdural haemorrhage

Submission date
21/04/2025

Recruitment status
No longer recruiting

Registration date
24/04/2025

Overall study status
Completed

Last Edited
24/04/2025

Condition category
Circulatory System

[_] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[X] Record updated in last year

Plain English summary of protocol

Background and study aims
This study aims to evaluate the effectiveness of single burr hole as compared to double burr hole craniostomy for chronic subdural hematoma (cSDH), an old clot of blood on the surface of the brain beneath its outer covering. The objectives are to determine the outcomes, risks and benefits of single burr hole as compared to double burr hole in cSDH patients, and to evaluate illness, death and complications in cSDH patients.

Who can participate?
Patients aged 18 years and over with chronic subdural haematoma

What does the study involve?
Participants were randomly allocated to undergo either single burr hole craniostomy or double burr hole craniostomy. Participants were monitored through follow-ups at 1 week and 1 month after surgery. The follow-up assessments were designed to evaluate the effectiveness of the surgeries, monitor recovery, and detect any complications or differences in success rates between the two methods.

What are the possible benefits and risks of participating?
There are no additional risks from the procedure as such. The study will help contribute to the standardisation of treatment as single burr hole craniostomy is a simple, less time-consuming and less invasive treatment.

Where is the study run from?
All India Institute of Medical Sciences, Patna

When is the study starting and how long is it expected to run for?
June 2022 to September 2024

Who is funding the study?
Investigator initiated and funded

Who is the main contact?
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Contact information

Type(s)
Public, Scientific, Principal investigator

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
Nil known

Study information

Scientific Title
A randomized controlled trial comparing the efficacy of single burr hole with double burr hole in the patients of chronic subdural hematoma

Acronym
SDCSDH

Study objectives

Single burr hole craniostomy is equally effective as double burr hole craniostomy and introduces lesser risk in treatment of chronic subdural hematoma (cSDH).

Ethics approval required
Ethics approval required

Ethics approval(s)
approved 21/06/2022, AIIMS Patna Ethical Committee (Division of Research, All India Institute of Medical Sciences, Patna, AIIMS Road, Patna, 801507, India; +91 (0)612 2451006; researchdivision@aiimspatna.org), ref: AIIMS/Pat/IEC/PGth/Jul22/16

Study design
Open randomized controlled trial

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Chronic subdural hematoma

Interventions
Participants were randomised by simple randomisation into two groups:
Group A: Double burr hole (frontal and parietal)
Group B: Single burr hole (parietal)

Radiological assessment (NCCT BRAIN) was done preoperatively, postoperatively at 6 hours and at the time of discharge. Patients were followed up at 1 week and 1 month post-discharge. Follow-up questionnaires (persistent headache, focal neurological deficit, seizure and altered level of consciousness) were filled in the master chart and evaluated further.

Intervention Type
Procedure/Surgery

Primary outcome(s)
1. Post-operative complications assessed at 6 hours, 1 week and 1 month post-intervention
2. Surgical site infection assessed using CDC criteria at 6 hours, 1 week and 1 month post-intervention
3. Persistence of headache assessed using the Headache Impact Test (HIT-6) at 1 month
4. Neurological deficit assessed using the Glasgow Coma Scale (GCS) at 1 month
5. Level of consciousness assessed using the Glasgow Coma Scale (GCS) at 1 month

Key secondary outcome(s))
1. ICU length of stay measured using patients' medical records
2. Hospital length of stay measured using patients' medical records

Completion date
30/09/2024

Eligibility

Key inclusion criteria
All diagnosed cases of chronic subdural hematoma

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Upper age limit
99 years

Sex
All

Total final enrolment
66

Key exclusion criteria
1. Patients with recurrent chronic subdural hematoma (cSDH)
2. Patients with asymptomatic chronic subdural hematoma (cSDH)
3. Patients with hematological disorders or those using anticoagulant drugs
4. Patients with septated membranes in chronic subdural hematoma (cSDH)
5. Patients with acute on chronic subdural hematoma (SDH)

Date of first enrolment
01/07/2023

Date of final enrolment
01/07/2024

Locations

Countries of recruitment
India

Study participating centre
All India Institute of Medical Sciences, Patna
Trauma Center
AIIMS Patna, AIIMS Road, Phulwari Sharif

Patna
India
801507

Sponsor information

Organisation
All India Institute of Medical Sciences, Patna

Funder(s)

Funder type
Other

Funder Name
Investigator initiated and funded

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study will be stored in a publicly available repository

IPD sharing plan summary
Stored in publicly available repository

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes
Protocol file			23/04/2025	No	No