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A randomized controlled trial comparing methods of bone flap preservation for cranioplasty in cases of traumatic brain injury

Submission date
18/01/2025

Recruitment status
No longer recruiting

Registration date
24/01/2025

Overall study status
Completed

Last Edited
22/01/2025

Condition category
Injury, Occupational Diseases, Poisoning

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

Plain English summary of protocol

Background and study aims
After a severe head injury, a procedure called decompressive craniectomy is often done to reduce pressure in the brain. During this surgery, a piece of the skull, called the bone flap, is removed and needs to be stored so it can be put back after 3 months, once the brain swelling goes down and the patient recovers. Many hospitals store the bone flap in freezers, and it is later sterilized and used in a follow-up surgery called cranioplasty. However, in hospitals with fewer resources, especially in low- and middle-income countries, freezers may not always be available or reliable. An alternative method is storing the bone flap under the skin of the patient' s abdomen or thigh also known as subcutaneous preservation. This study aims to compare the risks and outcomes of cranioplasty using bone stored in a freezer versus bone stored under the skin to find the better option in these settings.

Who can participate?
Patients aged 18 years and over admitted to AIIMS Patna Trauma Center who need to undergo decompressive craniectomy following traumatic brain injury

What does the study involve?
Participants are randomly allocated into two groups. Group A has their bone flap stored in a freezer and Group B has their bone flap stored in a pocket beneath the skin fat of the abdomen or thigh. Both groups of patients will undergo replacement of the skull bone after 3 months in a procedure known as cranioplasty. The outcomes after the cranioplasty will be measured up to day 30.

What are the possible benefits and risks of participating?
Despite its low prevalence, titanium hypersensitivity is a risk factor that may increase the risk of illness and death in cases of cranioplasty. Cases of infection or bone resorption can lead to complications such as hygroma (fluid-filled sac), meningitis (inflammation around the brain) or encephalitis (brain inflammation). There are also general operative risks as this study requires an operative intervention.
The study will help to determine the role of a method of preservation of bone in cranioplasty

that can be replicated in areas of poor health infrastructure. The study will help determine the factors contributing to complications and re-operations in cases of cranioplasty and help prevent them. The study will help contribute to the standardization of the treatment of cranial defects.

Where does the study run from?
AIIMS Patna Trauma Center (India)

When is the study starting and how long is it expected to run for?
February 2023 to December 2024

Who is funding the study?
Investigator initiated and funded

Who is the main contact?
Dr Rachith Sridhar, rachith92@gmail.com

Contact information

Type(s)
Public, Scientific, Principal Investigator

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
Nil known

Study information

Scientific Title
A randomized controlled trial comparing the use of cryopreserved and subcutaneously preserved bone flaps for cranioplasty in cases of traumatic brain injury to assess the rates of postoperative surgical site infection and neurological outcomes

Acronym
RCSCCP

Study objectives
Correction of cranial defects in cases of traumatic brain injuries with subcutaneously preserved bone flap will provide equal if not greater benefits when compared to cryogenically preserved flaps while remaining financially viable.

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 21/06/2023, Institutional Ethics Committee, All India Institute of Medical Sciencs, Patna (Research Division, AIIMS Patna, AIIMS Road, Patna, 801507, India; +91 (0)612-2351006; iecaiimspatna@gmail.com), ref: AIIMS/Pat/IEC/PGTh/July22/17

Study design
Interventional randomized controlled trial (non-blinded)

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

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

Health condition(s) or problem(s) studied
Patients with traumatic brain injury who need to undergo decompressive craniectomy

Interventions
After written informed consent from the patient or guardian of the patient who is planned for decompressive craniectomy following traumatic brain injury, the patient is allocated into one of the two groups by simple randomization via the method of sealed envelopes. Group A has their bone flap stored in a freezer at -18 degrees Celcius and Group B has their bone flap stored in a

subcutaneous pocket of the abdomen or thigh. Patients are recalled after 12 weeks of craniectomy and then taken up for cranioplasty with their respective bone flaps. The development of postoperative surgical site infection and neurological outcomes are assessed and recorded from the date of cranioplasty to 1 month via assessment in the ward and follow-up via outpatient visits.

Patients who die during the study period, are lost to follow-up, have pre-operative bone flap infection, develop any surgical contraindications or withdraw consent for any reason are removed from the final analysis.

Intervention Type
Procedure/Surgery

Primary outcome measure
1. Surgical site infection is assessed as "Yes" or "No" using clinical examination with the presence of surgical site infection defined by National Healthcare Safety Network Criteria on day 7 and day 30
2. Neurological outcome is measured using the Glasgow Outcome Score measured at baseline, day 7 and day 30

Secondary outcome measures
1. Drain output is measured in milliliters using a measuring cup on day 1
2. Seroma is assessed as "Yes" or "No" using the clinical presence of subgaleal fluctuation (physical examination) on day 7 and day 30
3. Re-operation is assessed as "Yes" or "No", defined by the presence of additional surgical interventions from the day of cranioplasty to day 30

Overall study start date
08/02/2023

Completion date
22/12/2024

Eligibility

Key inclusion criteria
1. Patients who undergo decompressive craniectomy following traumatic brain injury during the approved period in All India Institute of Medical Sciences, Patna
2. Patients who have provided written informed consent for participation in the study

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex

Both

Target number of participants
Group A: 50, Group B: 50, Total: 100

Total final enrolment
158

Key exclusion criteria
1. Patients presenting with shock due to trauma on initial presentation
2. Patients with additional indication of exploratory laparotomy
3. Patients with loss of scalp skin and soft tissue on the side of decompressive craniectomy.
4. Patients who have loss of skin or soft tissue involving both anterior abdominal wall and lateral aspect of both thighs
5. Preexisting loco-regional infections involving both anterior abdominal wall and both thighs on the day of decompressive craniectomy
6. Patients with loco-regional infections at the flap site or osteomyelitis of cranium
7. Patients who have developed proven brain abscess or meningitis
8. Patients who underwent decompression due to causes other than trauma
9. Bilateral cranial defects
10. History of radiation therapy
11. Patients with general operative contraindications and bleed dyscrasias

Date of first enrolment
22/06/2023

Date of final enrolment
22/09/2024

Locations

Countries of recruitment
India

Study participating centre
All India Institute of Medical Sciences, Patna
Trauma Office, First Floor
Department of Trauma Surgery and Critical Care
AIIMS Road, Phulwari Sharif
Patna
India
801507

Sponsor information

Organisation

All India Institute of Medical Sciences, Patna

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Sponsor type
Hospital/treatment centre

Website
https://aiimspatna.edu.in/

Funder(s)

Funder type
Other

Funder Name
Investigator initiated and funded

Results and Publications

Publication and dissemination plan
Planned publication in a peer-reviewed journal

Intention to publish date
05/02/2025

Individual participant data (IPD) sharing plan
Datasets generated and analyzed will be available on request from Dr Rachith Sridhar (rachith92@gmail.com)

IPD sharing plan summary
Available on request