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# Effectiveness of surgical procedures for acute cranial expansion in traumatic brain injury

**Submission date**
02/01/2025

**Recruitment status**
Recruiting

**Registration date**
01/04/2025

**Overall study status**
Ongoing

**Last Edited**
01/04/2025

**Condition category**
Circulatory System

[ ] 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
Traumatic brain injury (TBI) patients often exhibit an increase in their intracranial volume due to blood collection or brain tissue edema. When the volume of any intracranial compartment exceeds a critical threshold, the compensatory mechanisms become overwhelmed, compromising intracranial compliance and blood supply, which leads to intracranial compartment syndrome (ICCS) and further exacerbates brain damage through secondary injury. When less invasive measures to counteract ICCS prove insufficient, cranial decompression is recommended, with decompressive craniectomy (DC) currently being the preferred technique. Although its effectiveness has been demonstrated, DC is also associated with a high incidence of complications. Expansive craniotomy (EC) has been proposed as an alternative that leverages the benefits of cranial decompression provided by DC while reducing the associated adverse effects. This study will compare the functional outcomes and complications linked to DC and EC.

Who can participate?
Adults aged 18 to 70 years old with TBI diagnosed with ICCS who require cranial decompression

What does the study involve?
In DC a cranial vault bone graft is removed and left out to be stored in a bone bank or an abdominal pouch created during the surgery. In EC the cranial vault bone graft is fixed in an elevated position 1 - 1.5 cm above the cranial rim by 3-5 metallic plates placed during surgery. Participants' progress will be observed during their hospital stay and assessed for 1 year through structured telephone follow-ups. The main outcomes include functional recovery and the rate of complications such as operative site infections, and/or reinterventions. By comparing these two methods, the study seeks to determine whether the expansion craniotomy improves outcomes for TBI patients while maintaining or enhancing the safety and reliability of the cranial decompression procedure.

What are the possible benefits and risks of participating?
Participants may benefit from a safer and more effective method of reducing ICP, especially if they are assigned to the expansion craniotomy group. The study provides access to expert surgical care and close monitoring throughout the recovery process. Contributions to this research could lead to improved treatment protocols for future TBI patients worldwide.

Both procedures carry inherent surgical risks, including infection and bleeding, among others, not related to the study per se. Because the indications for any of the two interventions will be the same for the original procedure at the discretion of the treating neurosurgeon. Participants will be required to attend follow-up assessments, which may involve some time and effort. All procedures will be performed by experienced neurosurgeons following established safety protocols. Participants will be closely monitored, and any complications will be promptly addressed. This study represents an important step toward advancing surgical techniques for managing severe TBI and improving the quality of care for patients worldwide.

Where is the study run from?
Meditech Foundation in Cali (Colombia)

When is the study starting, and how long is it expected to run for?
December 2024 to February 2027

Who is funding the study?
NTPlast S.r.l.

Who is the main contact?
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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 comparative-effectiveness study on expansion craniotomy versus decompressive craniectomy for surgical management of traumatic brain injury in patients with intracranial compartment syndrome

### Acronym
E-SPACE-TBI

### Study objectives
This study aims to determine the outcomes of decompressive craniectomy versus expansion craniotomy in the surgical management of patients with TBI and intracranial compartment syndrome

### Ethics approval required
Ethics approval required

### Ethics approval(s)
approved 31/01/2025, Meditech Ethics and Research Committee (Calle 7A # 44-103, Cali, 760036, Colombia; +57 602 372 06 72; comitedeeticainvestigacion@meditechhubcol.org), ref: CEIM-2024-12-102

### Study design
Prospective multicentric observational comparative-effectiveness study

### Primary study design
Observational

### Study type(s)
Efficacy

### Health condition(s) or problem(s) studied
Intracranial compartment syndrome in traumatic brain injury patients

### Interventions

The study will include patients with traumatic brain injury and intracranial compartment syndrome managed either by hemispheric expansion craniotomy or hemispheric decompressive craniectomy.

Enrollment:
Participants are screened upon admission to the emergency room after experiencing a traumatic brain injury (TBI). Eligibility is determined using clinical and imaging criteria, including abnormal brain CT scans and evidence of intracranial compartment syndrome (ICCS), which is defined as a primary intracranial injury generating a loss of intracranial compliance and generating risk for brain tissue hypoxia and/or hypoperfusion. Informed consent is obtained from participants or their legal representatives as many of these patients can arrive with a low level of consciousness due to the TBI.

Surgical interventions: participants are allocated to one of two groups:
This study will conduct surgical procedures for cranial decompression to treat intracranial compartment syndrome. Different techniques can achieve this. Currently, decompressive craniectomy (DC) is the most frequently used technique. It is favored by the Brain Trauma Foundation's current guidelines and will serve as a comparator for expansion craniotomy (EC). The allocation of patients to the intervention they will undergo will be based on the clinical criteria of the treating neurosurgeon as long as the patients meet the inclusion criteria and do not present any exclusion criteria. Neurosurgeons will be required to describe the reason(s) why the surgery was indicated and why the surgical approach was selected.
The EC will be performed through a retro-auricular “C-shape” incision and executing a 15x15 cm craniotomy with a “C-shape” durotomy. Dural closure will be at the discretion of the surgeon and the availability of resources, including duroplasty with aponeurotic galea, a suturable dural patch, a non-suturable dural patch, or simply a superficial dural cover with hemostatic materials like Surgicel® or Gelfoam®. The expansion craniotomy will be finished with a cranioplasty using 3-5 “Rialto” plates for bone graft closure.
There are multiple techniques for DC. The elected technique will be at the discretion of the treating neurosurgeon, but only fronto-parieto-temporal DC will be considered. The removed bone flap may be stored in an abdominal pouch in the right or left upper abdominal quadrants or by freezing in a bone or blood bank freezer.
Patients who receive an EC may subsequently be taken to DC if the expected improvement is not achieved with the intervention, according to the postsurgical images and invasive and non-invasive neuromonitoring, based on the criteria of the treating neurosurgeon. If this happens, the treating neurosurgeon must specify why they opted for the procedure.
On the other hand, the intervention cannot be changed in patients taken to DC once the surgery is completed since the bone would have already been removed and stored.

Follow-up and monitoring:
Observation During Hospitalization: Patients with this type of procedure, always go for postoperative management to intensive care units (ICUs), independent of the study. Follow-up is performed by ICU personnel and includes systemic multi-monitoring and evaluations for postoperative complications such as infections. They regularly require head imaging control with CT not specifically associated with the study (is an observational CEI study). The data collectors of the study will be collecting physiological variables daily from the clinical records of the ICU. Data monitoring will be performed by the central research team in permanent contact with the local investigators.
Long-Term Follow-Up: Data will be collected from the medical record until the patient is discharged or transferred and by telephone interview at 3, 6, and 12 months after the admission. The telephone follow-up will include applying the Glasgow Outcome Scale—Extended version (GOSE) and evaluating functional recovery.

Duration:
Total Observation: Participants will be observed continuously during their hospital stay.

Data Collection and Sources:
Data will be collected from the medical records.
Demographic and Clinical Data: Includes age, sex, baseline health, and mechanism of trauma.
Surgical Outcomes: we will include complications reported in the medical record or observed inside the ICU.
Functional Outcomes: Evaluated from the medical records and GOSE scores.
Data Sources: Data will be collected from medical records, direct observations, and after discharge by telephone interviews conducted by trained personnel.

### Intervention Type
Procedure/Surgery

### Primary outcome(s)
Functional outcomes measured using the Glasgow Outcome Scale Extended at discharge, 3 months, 6 months, and 12 months after surgery

### Key secondary outcome(s))
1. Control of the Intracranial Compartment Syndrome measured using ICP waveform via invasive and noninvasive devices and/or noninvasive neuromonitoring techniques (digital pupillometry, optic nerve sheath diameter ultrasonographic measurement, and transcranial Doppler) measured daily during ICU admission.
2. Frequency and type of neurosurgical interventions required measured using data collected from medical records when possible and telephone follow-up as an alternative until the end of the follow-up at 12 months after the initial surgery
3. Medical and surgical treatment intensity measured according to the categories of stratified management of intracranial pressure proposed in the study methodology that are based on international guidelines for the management of intracranial hypertension at discharge from the ICU
4. Surgical site complications measured using data collected from medical records when possible and telephone follow-up as an alternative until the end of the follow-up at 12 months after the initial surgery
5. ICU and in-hospital length of stay collected from medical records at hospital discharge

### Completion date
01/02/2027

## Eligibility

### Key inclusion criteria
1. TBI patients arriving at the emergency room in the first 24 hours following trauma.
2. Abnormal CT scan, with a primary injury including any epidural, intracerebral or subdural collection with a midline shift >3 mm and any basal cistern compression with at least 2 abnormal findings in the initial evaluation at the emergency room including optic nerve ultrasound > 6 mm on the eye at the same side of the CT´s primary injury or and/or an abnormal pupillometry with a reduced MCV in the pupil of the same side of the CT´s primary injury, or/and a TCD with PI > 1.3 and/or MCA-DV < 20 cm/seg on the same side of the CT´s primary injury or/and a P2>P1 waveform pattern in the same side of the CT´s primary injury.
3. Age 18 to 70 years old.

4. Patients with or without polytrauma with survival expectancy >24 hours.
5. Cranial decompression or cranial expansion surgical procedures less than 24 hours after the trauma.

### Participant type(s)
Patient

### Healthy volunteers allowed
No

### Age group
Mixed

### Lower age limit
18 years

### Upper age limit
70 years

### Sex
All

### Key exclusion criteria
1. TBI patients arriving at the emergency room after 24 hours following trauma.
2. Normal CT scan at the emergency room.
3. Abnormal CT scan at the emergency room with any primary injury and midline shift less than 3mm or without basal cistern compression and with normal values in at least two different modalities of assessing ICCS (pupillometry, optic nerve sheath ultrasound, transcranial Doppler and/or non-invasive ICP waveform analyzer.
4. Age less than 18 or more than 70 years old.
5. Polytrauma or massive brain injury with survival expectancy < 24 hours.
6. Cranial decompression or cranial expansion surgical procedures performed > 24 hours after the trauma.

### Date of first enrolment
01/02/2025

### Date of final enrolment
01/02/2026

## Locations

### Countries of recruitment
Bolivia

Brazil

Cambodia

Cameroon

Chile

Colombia

Dominican Republic

Ecuador

Egypt

Guatemala

Italy

Nigeria

Paraguay

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# Sponsor information

**Organisation**
Meditech Foundation

# Funder(s)

**Funder type**
Industry

**Funder Name**
NTPlast

# 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 MR Dr Santiago Cardona (cardona.santiago.meditecf@outlook.com). Individual participant data (IPD) will be stored in a private repository and made available upon request. Once requested, the unprocessed data collected on the RedCap platform will be shared as soon as possible. The shared data will be anonymous, as the only identifier will be the ID assigned to patients participating in the study. No additional consents are required for sharing IPD, as this possibility is included in the informed consent form signed by patients or their next of kin during their involvement in the study.

## IPD sharing plan summary

Stored in non-publicly available repository, Available on request

## 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 |
| Study website | Study website | 11/11/2025 | 11/11/2025 | No | Yes |