

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

<b>Submission date</b> 02/01/2025	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 01/04/2025	<b>Overall study status</b> Ongoing	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
<b>Last Edited</b> 01/04/2025	<b>Condition category</b> Circulatory System	<input type="checkbox"/> Individual participant data <input checked="" type="checkbox"/> 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?

Dr Andrés M. Rubiano MD, PhD(c), FACS, IFAANS, direccion@meditechhubcol.org, andresrubiano@aol.com

## Contact information

### Type(s)

Scientific

### Contact name

Dr Santiago Cardona

### ORCID ID

<https://orcid.org/0000-0002-1446-0636>

### Contact details

Calle 7A #44-103

Cali

Colombia

760036

(+57) 324 593 1186

cardona.santiago.meditechf@outlook.com

### Type(s)

Principal investigator

### Contact name

Dr Andres M Rubiano

### ORCID ID

<https://orcid.org/0000-0001-8931-3254>

### Contact details

Calle 7A #44-103  
Cali  
Colombia  
760036  
+57 313 251 4132  
andresrubiano@aol.com

**Type(s)**

Public

**Contact name**

Ms Wendy Gonzalez

**ORCID ID**

<https://orcid.org/0009-0000-7106-3568>

**Contact details**

Calle 7A # 44-103  
Cali  
Colombia  
760036  
+57 310 537 4949  
gonzalez.wendy.meditechf@outlook.com

**Type(s)**

Scientific

**Contact name**

Dr Santiago Cardona

**Contact details**

Calle 7A #44-103  
Cali  
Colombia  
760036  
(+57) 324 593 1186  
proyectos@meditechhubcol.org

**Type(s)**

Principal investigator

**Contact name**

Dr Andres M Rubiano

**Contact details**

Calle 7a #44-103  
Cali  
Colombia  
760036  
(+57) 313 251 4132  
direccion@meditechhubcol.org

## 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 GOS-E 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

Peru

Philippines

Rwanda

Serbia

Tanzania

Thailand

Venezuela

**Study participating centre**

**Hospital Universitario del Valle Evaristo García**

Calle 5 #36-00

Cali

Colombia

760042

**Study participating centre**

**Hospital de Kennedy**

Av. 1 de Mayo #40B-54

Bogota

Colombia

110871



**Study participating centre**

**Clínica Santa Gracia**

Cl. 14 N #9-15

Popayan

Colombia

190003

**Study participating centre**

**Clinica Abel Gonzalez**

Av. Independencia # 101

Santo Domingo

Dominican Republic

10109

**Study participating centre**

**Hospital de Emergencia Jose Casimiro Ulloa**

Av. Roosevelt 6355

Lima

Peru

150122

**Study participating centre**

**Hospital Nacional Daniel Alcides Carrion**

Av. Guardia Chalaca 2176

Callao

Peru

07001

**Study participating centre**

**Hospital Belen de Trujillo**

Jiron Bolivar 350

Trujillo

Peru

13001

**Study participating centre**

**Hospital Miguel Pérez Carreño**

Av. San Martín, a la altura de Maternidad

Caracas

Venezuela

1020

**Study participating centre**  
**Hospital Central de Maracay**  
Av. Las Delicias, Maracay  
Maracay  
Venezuela  
2101

**Study participating centre**  
**Hospital Enrique Tejera**  
Av. Lisandro Alvarado  
Valencia  
Venezuela  
2001

**Study participating centre**  
**Hospital das Clínicas da FMUSP**  
Av. Dr. Enéas de Carvalho Aguiar, 255  
São Paulo  
Brazil  
05403-900

**Study participating centre**  
**Fundação Hospitalar Getúlio Vargas**  
Avenida Apurinã, número 4, en el barrio Praça 14 de Janeiro  
Manaus  
Brazil  
69020

**Study participating centre**  
**Hospital Obrero No. 1**  
Calle Lucas Jaimes 76  
La Paz  
Bolivia  
0000

**Study participating centre**  
**Hospital Regional San Juan de Dios**  
Calle Santa Cruz

Tarija  
Bolivia  
0000

**Study participating centre**  
**Hospital Clínico Mutual de Seguridad**  
Av. Libertador Bernardo O'Higgins  
Santiago de Chile  
Chile  
4848

**Study participating centre**  
**Hospital Puerto Montt**  
Los Aromos 65, Puerto Montt  
Los Lagos  
Chile  
5480000

**Study participating centre**  
**Hospital General San Juan de Dios**  
1ra Avenida "A" 10-50  
Ciudad de Guatemala  
Guatemala  
01010

**Study participating centre**  
**Hospital Roosevelt**  
Calzada Roosevelt  
Ciudad de Guatemala  
Guatemala  
01011

**Study participating centre**  
**Hospital del Trauma Prof. Dr. Manuel Giagni**  
Av Gral Máximo Santos  
Asunción  
Paraguay  
1500

**Study participating centre**  
**Hospital de Especialidades Eugenio Espejo**  
Av. Gran Colombia  
Quito  
Ecuador  
170403

**Study participating centre**  
**Hospital General Monte Sinai**  
Av. Gran Colombia  
Quito  
Ecuador  
170515

**Study participating centre**  
**Hospital General Docente Ambato**  
Av. Pasteur y Unidad Nacional  
Ambato  
Ecuador  
180104

**Study participating centre**  
**Hospital General Rodríguez Zambrano**  
Barrio Sta. Martha Calle 12 V-A San Mateo  
Manta  
Ecuador  
130213

**Study participating centre**  
**University College Hospital**  
Queen Elizabeth Road, Ibadan, Oyo State  
Ibadan  
Nigeria  
200212

**Study participating centre**  
**Rwanda Military Hospital**  
Street KK739ST, Kanombe, Distrito de Kicukiro  
Kigali  
Rwanda  
250

**Study participating centre**  
**Garoua Regional Teaching Hospital**  
Boulevard Docteur Jamot, Garoua, Región Norte  
Garoua  
Cameroon  
237

**Study participating centre**  
**El Qasr El Ainy Hospital**  
27 Nafezet Sheem El Shafaey St, Kasr Al Ainy  
Cairo  
Egypt  
11562

**Study participating centre**  
**Muhimbili Orthopaedic Hospital**  
Kalenga Street, West Upanga,  
Dar es Salaam  
Tanzania  
141111

**Study participating centre**  
**Bicol Regional Hospital and Medical Center**  
Rizal St. 4501  
Daraga  
Philippines  
4501

**Study participating centre**  
**Techo Santepheap National Hospital**  
JRC6+JR Win Win Blvd, Phnom  
Penh  
Cambodia  
12000

**Study participating centre**  
**Khon Kaen Hospital**  
54 Sri Chant Rd, Nai Mueang, Mueang Khon Kaen District

Khon Kaen  
Thailand  
40000

**Study participating centre**  
**Neurosurgical Clinic University Clinical Centre of Serbia**  
Dr Koste Todorovića 4  
Belgrade  
Serbia  
11000

**Study participating centre**  
**Ozienda Ospedaliero – Universitaria Policlinico Umberto I**  
Viale del Policlinico, 155, 00161  
Rome  
Italy  
00161

**Study participating centre**  
**Centro Diagnóstico de Especialistas**  
Cl. 13 #1175  
Riohacha  
Colombia  
440009

## **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?
<a href="#">Participant information sheet</a>	Participant information sheet	11/11/2025	11/11/2025	No	Yes
<a href="#">Study website</a>	Study website	11/11/2025	11/11/2025	No	Yes