

# Security and effectiveness assessment of locking systems in ventriculostomy for traumatic brain injury

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<b>Registration date</b> 03/04/2025	<b>Overall study status</b> Ongoing	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
<b>Last Edited</b> 03/04/2025	<b>Condition category</b> Circulatory System	<input type="checkbox"/> Individual participant data <input type="checkbox"/> Record updated in last year

## Plain English summary of protocol

### Background and study aims

This study focuses on traumatic brain injuries (TBI), a condition that can cause severe intracranial pressure and life-threatening complications. This study aims to compare the effectiveness and safety of a standard intervention called ventriculostomy for managing increased intracranial pressure (ICP) in patients with severe traumatic brain injury (TBI). Elevated ICP is a critical condition that can result in brain damage or death if not treated promptly. The goal is to reduce complications like catheter displacement and improve outcomes for patients with intracranial compartment syndrome (ICCS).

### Who can participate?

Adults aged 18 to 70 years old with confirmed ICCS caused by TBI

### What does the study involve?

The intervention will be performed in a traditional standard way or with an additional device called a catheter locking system. The first approach, standard ventriculostomy, involves placing a catheter into the brain's ventricular system to drain cerebrospinal fluid (CSF), thereby reducing ICP. The second approach incorporates the same catheter plus a catheter-locking device designed to secure the catheter in place, potentially reducing complications such as catheter displacement and the need for additional surgeries. Participants in this study will undergo either standard ventriculostomy or ventriculostomy with the locking device. Their progress will be observed during their hospital stay until the catheter is taken out (regularly on days 5th to 7th after the initial surgery) and assessed over the course of 1 year through structured telephone follow-ups. The main outcomes include functional recovery and the rate of complications such as operative site infections, catheter displacement, and/or reinterventions. By comparing these two methods, the study seeks to determine whether the locking device improves outcomes for TBI patients while maintaining or enhancing the safety and reliability of the procedure.

### What are the possible benefits and risks of participating?

Participants may benefit from a more stable and effective method of reducing ICP, especially if they are assigned to the locking device 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, bleeding, or complications related to catheter placement and not 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 neurosurgeon on call. 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?

The study is conducted across multiple international centers, including countries with both high- and low-resource settings.

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. (Italy)

Who is the main contact?

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

## Contact information

### Type(s)

Principal investigator

### Contact name

Dr Andrés M Rubiano

### ORCID ID

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

### Contact details

Calle 7A # 44-103

Cali

Colombia

760036

+ 57 3006154775

rubianoam@outlook.com

### Type(s)

Scientific

### 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)**

Public

**Contact name**

Mr Santiago Cardona

**Contact details**

Calle 7A # 44-103

cali

Colombia

760036

+ 57 324 59 31186

cardona.santiago.meditechf@outlook.com

**Type(s)**

Scientific

**Contact name**

Ms Wendy Gonzalez

**Contact details**

Calle 7A # 44-103

Cali

Colombia

760036

+57 310 537 4949

proyectos@meditechhubcol.org

**Type(s)**

Principal investigator

**Contact name**

Dr Andrés 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

### Protocol serial number

Nil known

## Study information

### Scientific Title

Comparative effectiveness study on catheter locking device versus standard ventriculostomy for surgical management of traumatic brain injury patients with intracranial compartment syndrome

### Acronym

SEALS-TBI

### Study objectives

The objective of this study is to determine the outcomes of standard ventriculostomy versus the use of a locking system for the ventricular catheter 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-2024-12-101

### 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 standard ventriculostomy or ventriculostomy plus a locking system device.

## Methodological Description:

### 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 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 Intervention:

Participants are assigned to one of two groups:

**Standard Ventriculostomy:** Involves inserting a catheter into the brain's ventricular system to drain cerebrospinal fluid (CSF) and reduce intracranial pressure (ICP). This is a common procedure performed in this type of patient. Do not include a novel technique.

**Ventriculostomy with a Locking Device:** This intervention is the same procedure, but it will be performed with an additional approved device, a locking system that secures the catheter in place, reducing the risk of displacement and associated complications.

The system requires internal approval by regulatory entities in each of the participant countries. Most of them already have approval and the others are in an internal approval process.

Countries cannot start collecting data until they have the internal government approval for the device distribution by internal medical suppliers.

### 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 multimonitoring and they evaluate catheter functionality, and complications such as infections or displacement. 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 and descriptions of catheter integrity on a daily basis from the clinical records of the ICU. The follow-up will include the first two weeks after surgery, but in general, these types of catheters do not remain in place for more than 8 days. Regularly they are taken out by the neurosurgery service between 5 to 7 days after insertion. 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 discharge or transfer of the patient and by telephone interview at 3, 6, and 12 months after the admission. The telephone follow-up will include the application of the Glasgow Outcome Scale - Extended version (GOSE), and evaluations of 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:** Will include the catheter placement, patency and complications if any 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 intracranial compartment syndrome measured using ICP waveform via invasive and non-invasive devices and/or non-invasive neuromonitoring techniques (digital pupillometry, optic nerve sheath diameter ultrasonographic measurement and transcranial Doppler) 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 from the ICU according to the categories of stratified management of intracranial pressure proposed in the study methodology that is based on international guidelines for the management of intracranial hypertension at discharge
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 measured using data collected from medical records at hospital discharge

### **Completion date**

28/02/2027

## **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 from 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 a 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**

30/04/2025

**Date of final enrolment**

01/02/2027

**Locations****Countries of recruitment**

United Kingdom

England

Bolivia

Brazil

Cambodia

Cameroon

Chile

China

Colombia

Dominican Republic

Ecuador

Egypt

Guatemala

India

Italy

Mexico

Nigeria

Paraguay

Peru

Philippines

Rwanda

Serbia

South Africa

Spain

Tanzania

Thailand

United States of America

Venezuela

**Study participating centre**

**Hospital Universitario del Valle Evaristo García**

Calle 5 ·#36-08

Cali

Colombia

760042

**Study participating centre**

**Hospital de Kennedy**

Carrera 78 #41A-85 Sur

Bogota  
Colombia  
110871

**Study participating centre**

**Clínica Santa Gracia**  
Calle 14 Norte #9-15  
Popayan  
Colombia  
190003

**Study participating centre**

**Clinica Abel Gonzalez**  
Avenida 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 Apuriná, 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****Azienda Ospedaliero-Universitaria Policlinico Umberto I**

Viale del Policlinico, 155, 00161 Roma RM, Italia

Rome

Italy

0649971

**Study participating centre****Neurosurgical Clinic University Clinical Centre of Serbia**

Dr Koste Todorovića 4, Beograd

Belgrado

Serbia

11000

**Study participating centre****Centro Diagnóstico de Especialistas Ltda**

Calle 13 No. 11-75, Riohacha, Guajira

Riohacha

Colombia

440001

**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 MS Dr Wendy Gonzalez (gonzalez.wendy.meditcf@outlook.com). Participant-level data (IPD) collected during the study will be securely stored in a private repository managed using institutional REDCap software based on our internal server. The server and the repository are not publicly accessible, ensuring the confidentiality and protection of participant information. The data will be organized and maintained according to strict data management protocols, including anonymization procedures to remove personally identifiable information. Access to the repository will be limited to authorized personnel involved in the study, and all data usage will comply with ethical and legal standards. Additional details about data sharing, including the timing of availability and any restrictions, will be included in the study record once finalized. Databases for the study will be available upon request to any of our standard channels of communication.

## 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="#">Study website</a>	Study website	11/11/2025	11/11/2025	No	Yes