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

Submission date 02/01/2025	**Recruitment status** Recruiting	[X] Prospectively registered [_] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [X] Record updated in last year
Registration date 03/04/2025	**Overall study status** Ongoing	
Last Edited 03/04/2025	**Condition category** Circulatory System	

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

Study website
https://seals-tbi-study.com/

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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
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

Secondary study design
Comparative-effectiveness study

Study setting(s)

Hospital, Medical and other records, Telephone

Study type(s)
Efficacy

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

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 measure
Functional outcomes measured using the Glasgow Outcome Scale Extended at discharge, 3 months, 6 months, and 12 months after surgery

Secondary outcome measures
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

Overall study start date
27/12/2024

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

Age group
Mixed

Lower age limit
18 Years

Upper age limit
70 Years

Sex
Both

Target number of participants
292

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

Bolivia

Brazil

Cambodia

Cameroon

Chile

China

Colombia

Dominican Republic

Ecuador

Egypt

England

Guatemala

India

Italy

Mexico

Nigeria

Paraguay

Peru

Philippines

Rwanda

Serbia

South Africa

Spain

Tanzania

Thailand

United Kingdom

United States of America

Venezuela

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Sponsor type
Research organisation

Website
https://www.meditechfoundationglobal.org/

Funder(s)

Funder type
Industry

Funder Name
NTPlast

Results and Publications

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

Intention to publish date
28/02/2028

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.meditecf@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