ISRCTN13566520 https://doi.org/10.1186/ISRCTN13566520

Association of intensive care nursing activities and brain pressure in patients with traumatic brain injury

Submission date
03/02/2026

Recruitment status
Recruiting

Registration date
04/02/2026

Overall study status
Ongoing

Last Edited
04/02/2026

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
Moderate to severe traumatic brain injury (TBI) requires intracranial pressure (ICP) monitoring to prevent secondary brain injuries. While nursing interventions (such as repositioning or suctioning) are essential, they can trigger ICP elevations. This study aims to objectively quantify the ICP dose ≥22 mmHg (cumulative burden) specifically associated with these five nursing care. We also aim to identify which interventions most frequently lead to ICP values ≥22 mmHg and how long these elevations persist, in order to optimize neuroprotective nursing strategies.

Who can participate?
Adult patients (aged 18 years and over) admitted to the ICU with a diagnosis of moderate- to-severe TBI requiring invasive mechanical ventilation and continuous invasive ICP monitoring

What does the study involve?
High-resolution ICP signals (100 Hz) will be recorded continuously. For five specific nursing interventions (body hygiene, repositioning, tracheal suctioning, oral care, and dressing changes), nurses will manually time-stamp the start and end of the procedure on the monitor. The ICP dose and the percentage of time spent above 22 mmHg will be analyzed for each episode and for each patient during the ICU stay.

What are the possible benefits and risks of participating?
Benefits: There is no direct therapeutic benefit for participants. However, the study will help improve future nursing protocols and neuroprotection for TBI patients.
Risks: This is a non-interventional, observational study. It does not modify standard clinical care; therefore, it carries no additional physical risk to the patient. Data privacy will be strictly maintained.

Where is the study run from?
Beaujon Hospital (France)

When is the study starting and how long is it expected to run for?
November 2025 to June 2027

Who is funding the study?
Beaujon Hospital (France)

Who is the main contact?
Myriam Lamamri, dorssaf.lamamri@aphp.fr

Contact information

Type(s)
Principal investigator, Scientific, Public

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Study information

Scientific Title
Association between intensive care nursing interventions and intracranial pressure in mechanically ventilated patients with moderate to severe traumatic brain injury

Acronym
PIC-NURSE

Study objectives
The first aim of PIC-Nurse will be to investigate the effect of five selected intensive care nursing interventions on the intracranial pressure (ICP) dose (above 22 mmHg) of moderate to severe mechanically ventilated traumatic brain injury patients in the ICU.

The second aim will be :
1. To determine the percentage of time spent with an ICP ≥22 mmHg during nursing interventions
2. To identify the specific types of nursing interventions (e.g., body hygiene, endotracheal suctioning, repositioning) most frequently associated with an ICP dose above ≥22 mmHg

3. To evaluate the mean duration of intracranial pressure (ICP) elevations ≥22 mmHg per nursing care episode
4. To analyze the clinical and therapeutic factors associated with an ICP dose exceeding 22 mmHg during nursing care
5. To evaluate patient prognosis (mortality and 6-month GOSE) according to the percentage of time spent with an ICP ≥22 mmHg during nursing interventions.

Ethics approval required
Ethics approval required

Ethics approval(s)
approved 07/08/2025, Ethics Committee for Research in Anesthesia and Intensive Care (SFAR – 74 rue Raynouard, Paris, 75016, France; -; cerar@sfar.org), ref: IRB 00010254 2025 – 116

Primary study design
Observational

Secondary study design
Cohort study

Study type(s)

Health condition(s) or problem(s) studied
Traumatic brain injury

Interventions
This prospective, monocentric, observational study will be conducted in a level 1 Trauma center in France. The study workflow is designed to integrate routine clinical practice without modifying standard care.

Following a comprehensive literature review and focus group sessions with experienced ICU nurses, we identified five nursing interventions potentially associated with intracranial hypertension (ICH). These procedures were selected based on their clinical frequency and their potential impact on intracranial pressure dynamics:
1. Body hygiene (bed bath and cleaning)
2. Patient repositioning and mobilization (turning and lateral positioning)
3. Endotracheal suctioning
4. Oral care
5. Dressing changes

All adult patients (≥18 years) admitted with moderate-to-severe TBI (GCS ≤12) and invasive ICP monitoring will be screened. Once included, their demographic data, injury severity (ISS, SAPS II, AIS head, Marshall score), implemented treatments, prognostic (ICU mortality, GOSE at ICU discharge, GOSE at 6 months) will be recorded.

Immediately following the insertion of the intracranial pressure (ICP) sensor, high-resolution waveform data will be continuously recorded at a sampling rate of 100 Hz throughout the entire duration of the neuromonitoring period.
For each nursing intervention, the nurse or nursing assistant performing the care will manually trigger a specific event marker on the monitor. This ensures precise time-stamping of the start and end of the procedure. During each care episode, the following data will be logged directly

into the monitoring system:
1. Exact onset and offset times of the intervention.
2. Type of nursing care performed (selected from the predefined list).

All recorded data will be stored in a secure, encrypted file accessible only to one study investigator. To ensure data integrity and prevent observational bias, analysis of the high-frequency signals will be conducted only upon completion of the final patient’s recording.

Intervention Type
Other

Primary outcome(s)
1. The ICP dose is defined as the cumulative pressure-time burden exceeding the 22 mmHg threshold, expressed in mmHg×h measured using Intracranial pressure monitor measured using intracranial pressure monitor at continuously from the admission until ICP monitoring discontinuation

Key secondary outcome(s))
1. Percentage of time during the nursing care spent with ICP ≥22 mmHg measured using intracranial pressure monitoring at continuously from the admission until ICP monitoring discontinuation

2. P2/P1 ratio measured using intracranial pressure monitoring at continuously from the admission until ICP monitoring discontinuation

3. Duration of mechanical ventilation measured using number of days on invasive mechanical ventilation at from the admission until ICU discharge

4. ICU length of stay measured using number of days in ICU at from the admission until ICU discharge

5. ICU mortality measured using the hospital's official Death Registry (electronic medical records) at from the admission until ICU discharge

6. Neurological and functional outcome measured using the Extended Glasgow Outcome Scale (GOSE) at ICU discharge and at 6 months

Completion date
30/06/2027

Eligibility

Key inclusion criteria
1. Adult patients (≥18 years old) admitted to the department of Intensive Care with a diagnosis of moderate-to-severe traumatic brain injury (TBI), defined by an admission Glasgow Coma Scale score ≤12
2. Patients requiring invasive mechanical ventilation at ICU admission
3. Patients managed with invasive intracranial pressure monitoring with an intraparenchymal sensors

Healthy volunteers allowed

Yes

Age group
Mixed

Lower age limit
18 years

Upper age limit
100 years

Sex
All

Total final enrolment
0

Key exclusion criteria
1. Patients without invasive intracranial pressure monitoring with an intraparenchymal sensors
2. Patients with an estimated life expectancy of less than 48 hours

Date of first enrolment
03/11/2025

Date of final enrolment
31/12/2026

Locations

Countries of recruitment
France

Study participating centre
Hôpital Beaujon
100 Boulevard du général Leclerc
Clichy
France
92110

Sponsor information

Organisation
Hôpital Beaujon

ROR

https://ror.org/03jyzk483

Funder(s)

Funder type

Funder Name
Hôpital Beaujon

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 the corresponding author.
Contact for access: Dr Myriam Lamamri (dorssaf.lamamri@aphp.fr).
Type of data: De-identified raw datasets used for the analysis.
Availability: Data will be available upon reasonable request following the completion of the final data analysis.
Consent and anonymization: In accordance with French regulations for observational research, patients are provided with an information leaflet and have the right to object to the use of their data. Any patient expressing opposition will be excluded from the dataset. All shared data are fully anonymized and stored in password-protected, encrypted Excel files to ensure security.

IPD sharing plan summary
Available on request