

# INPLASY PROTOCOL

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**Review Stage at time of this  
submission:** Formal screening  
of search results against  
eligibility criteria.

**Conflicts of interest:**  
None declared.

## Effectiveness of Early Tracheostomy compared with Late Tracheostomy Or Prolonged Orotracheal Intubation in Traumatic Brain Injury: Protocol of Umbrella Review

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**Review question / Objective:** What is the effectiveness of  
Early Tracheostomy compared with Late Tracheostomy Or  
Prolonged Orotracheal Intubation in Traumatic Brain Injury?

**Eligibility criteria:** The inclusion criteria are (P) studies with  
patients above 18 years old, male or female, who had a severe  
traumatic brain injury and who need advanced airway  
support; (I) patient undergoing early tracheostomy (less than  
10 days of oro-traqueal intubation); (C) patient undergoing late  
tracheostomy (after 10 days of oro-traqueal intubation) or  
undergoing prolonged intubation; (O) With data about  
mortality, time on ICU stay, on Hospital stay and time free of  
mechanical ventilation, complications related a health care  
services (pneumonia, septicemia, candidemia, Pressure  
ulcers, thromboembolic events and time using antibiotics),  
Quality of life (scores about neurological functions); e (S)  
Systematic reviews. No language restrictions. The exclusion  
criteria are data about mortality without data about time and  
follow up (In Hospital or after discharge?). We will contact the  
authors of studies without data enough to make a decision or  
without full text available, If we do not have answers we will  
exclude the study.

**INPLASY registration number:** This protocol was registered with  
the International Platform of Registered Systematic Review and  
Meta-Analysis Protocols (INPLASY) on 24 August 2022 and was  
last updated on 24 August 2022 (registration number  
INPLASY202280096).

### INTRODUCTION

**Review question / Objective:** What is the  
effectiveness of Early Tracheostomy  
compared with Late Tracheostomy Or

Prolonged Orotracheal Intubation in  
Traumatic Brain Injury?

**Condition being studied:** Traumatic Brain  
Injury (TBI) is every traumatic anatomical  
ou functional injury that affects brain, skull

and/or vessels related to them. TBI is a public health problem that involves over 50 million people per year in Worldwide.

## METHODS

**Participant or population:** Traumatic Brain Patients with advanced airway support.

**Intervention:** Early tracheostomy (less than 10 days of orotracheal intubation)

**Comparator:** Late tracheostomy (more than 10 days of orotracheal intubation) OR Prolonged Orotracheal Intubation.

**Study designs to be included:** Systematic review with metaanalyses.

**Eligibility criteria:** The inclusion criteria are (P) studies with patients above 18 years old, male or female, who had a severe traumatic brain injury and who need advanced airway support; (I) patient undergoing early tracheostomy (less than 10 days of orotracheal intubation); (C) patient undergoing late tracheostomy (after 10 days of orotracheal intubation) or undergoing prolonged intubation; (O) With data about mortality, time on ICU stay, on Hospital stay and time free of mechanical ventilation, complications related a health care services (pneumonia, septicemia, candidemia, Pressure ulcers, thromboembolic events and time using antibiotics), Quality of life (scores about neurological functions); e (S) Systematic reviews. No language restrictions. The exclusion criteria are data about mortality without data about time and follow up (In Hospital or after discharge?). We will contact the authors of studies without data enough to make a decision or without full text available, If we do not have answers we will exclude the study.

**Information sources:** PUBLISHED DATABASES (Medline by PUBMED, Lilacs, Dare-Cochrane, Scopus by Elsevier, Web Of Science e Embase by Elsevier) NON-PUBLISHED (Open Grey by Sigle; Clinical Trial Register at the International Clinical Trials Registry Platform) (Referencies of the selected studies).

**Main outcome(s):** Mortality: Number of deaths on Hospital or after discharge related with traumatic brain injury.

**Additional outcome(s):** Secondaries outcomes: \* frequency of complications related to UCI stay and duration of mechanical ventilation (number of events of Pneumonia, Septicemia, Candidemia, Pressure ulcers, thromboembolic events) \* time (in days) on ICU stay \* time (in days) on Hospital stay \* time (in days) free of mechanical ventilation \* time (in days) of using antibiotics \* Quality of life (scores about neurological functions) Tertiary variables (Age, sex, time of follow up, neurosurgical interventions, APACHE II, Glasgow Coma Scale, Injury Severity Score).

**Data management:** One reviewer (RRA) will select the studies and other reviewer (IHAA) will check the selection. These reviewers will solve disagreements by means of meetings and consensus. A third and more experienced reviewer (OBON) will be consulted when disagreements persist. The same two reviewers (RRA and OBON) will also perform data extraction using pre established forms, where the following data will be extracted: - Title

- Authors
- Journal
- Number
- Year
- Pages
- Database found

\*Specific data:

- Aim
- Type of study
- Inclusion and exclusion criteria
- Patients' features
- Intervention and comparison
- Description of outcomes
- Assessment of outcomes
- Risk of bias of the systematic review using the Robis Tool
- Methods of study selection
- Methods of methodological quality assessment or risk of bias assessment of primary studies.

\* Statistical data:

- Continuous outcomes

- Categorical outcomes
- Results from meta-analysis
- \* Conclusions of the study- Title
- Authors
- Journal
- Number
- Year
- Pages
- Database found
- \*Specific data:
  - Aim
  - Type of study
  - Inclusion and exclusion criteria
  - Patients' features
  - Intervention and comparison
  - Description of outcomes
  - Assessment of outcomes
  - Methods of study selection
  - Risk of bias analyses
- \* Statistical data:
  - Continuous outcomes
  - Categorical outcomes
- \* Conclusions of the study

**Quality assessment / Risk of bias analysis:** According to ROBIS tool, the risk of bias can be classified as high, low or unclear.

**Strategy of data synthesis:** The Cohen's kappa statistics will be performed to measure the level of agreement between reviewers for the selection of eligible studies and for the risk of bias assessment. MetaXL 5.3 (Epigear, Queensland, Australia) will be used to metanalyses. To dichotomic outcomes we will calculate Relative Risk (RR) for prospective studies, and Odds Ratio (OR) for retrospective studies (Confidence Interval 95%). To continuous outcomes will be calculated Mean Difference or standardized mean difference (Confidence Interval 95%). Predicting a possible heterogeneity between studies, the random effects model will be used. Heterogeneity will be analysed by Q's Cochrane with p value related and will be measured by Higgins Test (I<sup>2</sup>). Will be reported as small (I<sup>2</sup>70%). The publication bias will be accessed with DOI-plot and LFK index. To solve heterogeneity will be performed a sensitivity analysis.

**Subgroup analysis:** Time of follow up, Age, Glasgow Coma Scale, Injury Severity Score, Type of complications.

**Sensitivity analysis:** Based on risk of bias/ Quality assessment Published vs Non Published studies.

**Language restriction:** No restrictions.

**Country(ies) involved:** Brazil.

**Keywords:** Early Tracheostomy ; Traumatic Brain Injury ; Mortality.

**Dissemination plans:** Journal of Neurotrauma, Intensive Care and Revista Brasileira de Medicina Intensiva.

**Contributions of each author:**

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Author 7 - CÉLIO FERNANDO DE SOUSA-RODRIGUES - RESPONSIBLE FOR PROTOCOL AND DRAFT THE MANUSCRIPT.