IRB #:026-300 April 2026

Protocol Title: Safety and efficacy of chemoprophylaxis in the presence of spinal epidural hematoma in traumatic spinal injuries.

Principal Investigator
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Sub-Investigators
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Study Location
Baylor University Medical Center (BUMC) â€“ Primary Site
Multicenter study in collaboration with the Western Trauma Association

Background (Rationale/Purpose)

Patients with spinal trauma are at an increased risk of venous thromboembolism (VTE). Modern series show a deep venous thrombosis (DVT) rate of about 15%.[1-4] The most feared complication of VTE is a pulmonary embolus which while more rare than DVT has been shown to be the third highest cause of death within the first year of spinal cord injury.[5] Early chemoprophylaxis has been shown to be both safe and effective in reducing VTE complications in patients suffering from spinal trauma.[6-14]

Approximately 0.5-1.7% of patients with spinal injuries will present with a traumatic spinal epidural hematoma (sEDH).[15] Current literature assessing the safety and efficacy of chemoprophylaxis either exclude these patients or have such small numbers that uncertainty remains, and clinical practice varies regarding VTE prophylaxis.

Research Question

1. To define the safety and efficacy of early VTE chemoprophylaxis in patents presenting with traumatic sEDH.

Aims and Objectives

1. We hypothesize that starting chemoprophylaxis within the first 48 hrs of admission will result in a decrease in VTE complications.
2. We further hypothesize that early chemoprophylaxis will not be associated with progression of sEDH.

Study Endpoints

1. Efficacy - Incidence of DVT and / or PE during acute hospitalization.
2. Safety â€“ radiologic worsening of sEDH; worsening of neurologic exam; need to return

to OR for hemorrhagic complication related to sEDH.

Study Design

This study will be designed as a multicenter prospective observational study conducted through the Western Trauma Association with BUMC as the primary site. Participants will be included in this observational study if they present to a participating trauma center with a traumatic spinal epidural hematoma determined via imaging obtained during the initial 24hr post injury and meet the remaining inclusion and exclusion criteria outlined below. Participating sites will collect the data points outlined in the data collection tool for each qualifying patient and subsequently upload the de-identified data to a centralized REDCap project created by the BUMC key study personnel.

Each participating site will obtain individual IRB approval to collect the data points listed in the data collection tool provided by BUMC. Data use agreements will be utilized with centers collaborating on this study who require a DUA to share de-identified data.

Sample Size

Based on a power analysis detailed below we are setting our accrual goal at 660 patients. A two-group study design will be used to test for difference in incidence of DVT between the two groups (early VTE chemoprophylaxis vs delayed). The comparison will be made using a two-tailed, two-sample Z-test with unpooled variance, with a Type I error rate (Î±) of 0.05. Using modern series DVT rate of about 15% as baseline (control) rate and assuming early VTE chemoprophylaxis will result in a 50% reduction in DVT, we estimate a total sample size of 550 (275 per group) will be required at 80% power. To account for clustering of patients within hospitals, the estimated sample size will be multiplied by variance inflation factor (VIF) of 1.2 to obtain final required sample size.

Study Group Definition/Eligibility Criteria (Inclusion/Exclusion/Study discontinuation criteria)Â Â Â Â Â Â Â Â Â Â Â Â Â Â

Inclusion Criteria

- Patient admitted to a level 1 or 2 trauma center.
- The patient is â‰¥18 years old
- Presence of traumatic spinal epidural hematoma on imaging obtained during the initial 24 hrs post injury.

Exclusion Criteria

- The patient is <18 years old
- The patient is currently pregnant
- The patient is currently incarcerated
- The patient is on therapeutic anticoagulation prior to hospitalization
- The patient has a prior history of VTE.

Premature termination/suspension of study

- Determination of unexpected, significant, or unacceptable risk to subjects
- Determination of futility
- Determination of significance prior to total enrollment.

Potential Risks

The most likely risks posed to subjects would be a breach of confidentiality if someone other than the research team obtained access to the data.

Potential Benefits

The research gathered will fill an important gap in the literature. Patients with spinal injuries are high risk for VTE and prophylaxis efficacy and safety is unclear in patients with sEDH. No studies exist in current literature that address this specific patient population.

Risk to Benefit

Risk to benefit is acceptable as this data entry will not affect current or past care of the patient. These findings will help determine optimal treatment procedures for future patients.

Data Collection and management

Data from the Baylor University Medical Center Trauma Registry and EPIC electronic medical record system will be entered into the REDCap database. The timeline for data collection is from 6/1/2026 to 6/1/2031, and the approximate number of records to be reviewed is 500. A REDCap ID will be used to avoid using PHI to identify patients. Only key study personnel will have access to this password protected database. Collaborating centers will also input their data to redcap in the same manner. Each center will obtain IRB approval from their institution and execute a DUA with Baylor University Medical Center. Accounts for participating site research personnel will be requested from the BSW REDCap team, which will then be subsequently grouped by Data Access Groups to ensure that they are only able to manage/view data from their institution.

A waiver of informed consent is requested for this study as the research complies with 45 CFR 46.117(c): involves no more than minimal risk given this is an observational study in which only medical records will be reviewed.

Study Methods/Procedures

Data will be collected with the assistance of electronic medical/health record. All data collected from BUMC databases will be entered into REDCap. Data from participating institutions will be entered into the same REDCap project under a specific Data Access Group (DAG) with a corresponding site ID so that they may only enter, view, and edit data from their own center. Data from Baylor University Medical Center will be deidentified with a REDCap ID and a record of corresponding MRNs will be kept on a secure hospital server. Once data collection is complete, the MRNs corresponding w/ REDCap IDs will be deleted. All data collection methodologies will be maintained under strict surveillance and will be encrypted. Data supplied to the REDCap database from other institutions will be deidentified.

Statistical Analysis Plan

Descriptive statistics (means, standard deviations, frequencies, and proportions) will be used to summarize participant characteristics and responses across key variables.

Comparisons between two groups will be conducted using independent sample t-tests or Mann-Whitney U tests, as appropriate. For comparisons involving more than two groups one-way ANOVA or Kruskal Wallis tests will be used. Associations among categorial variables will be assessed using Chi-square or Fisherâ€™s exact tests, as appropriate.

Multiple linear regression models will be used for adjusted analysis of multiple predictors

on continuous outcomes. Logistic regression analysis will be used to model adjusted effect of patient characteristics on binary outcomes. All analyses will be conducted using a two-tailed significance threshold of 0.05. All statistical analyses will be performed using SAS v. 8.4.

Funding Source

Payment for all activities will come from the trauma services research budget. No additional funding is required.

Confidentiality and Privacy

Participant confidentiality will be strictly maintained at all times. Compliance with HIPAA guidelines will always be enforced. Information will only be accessed by the principal investigator or sub-investigators. No identifiable patient data will be disclosed. All information obtained will be source de-identified, presented on a large scale, and not traceable to any one particular individual. All data collected will be kept on the password protected hospital server, and only authorized trained personnel will have access to the share drive. If physical records are collected, they will be stored in locked file cabinets. At close of this study, all identifiers will be removed from the data collection tools.

References

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