



Initial Review

Approval Ends:
1/28/2026

IRB Number:
100217

TO: Danielle Detelich, MD
Trauma and Acute Care Surgery Services
PI phone #: 630-643-6841

PI email: Danielle.Detelich@uky.edu
FROM: Chairperson/Vice Chairperson
Medical Institutional Review Board (IRB)
SUBJECT: Approval of Protocol
DATE: 1/29/2025

On 1/29/2025, the Medical Institutional Review Board approved your protocol entitled:

2025 Blunt Cerebrovascular Injury Antithrombotic Therapy in Trauma

Approval is effective from 1/29/2025 until 1/28/2026 and extends to any consent/assent form, cover letter, and/or phone script. If applicable, the IRB approved consent/assent document(s) to be used when enrolling subjects can be found on the approved application's landing page in E-IRB. [Note, subjects can only be enrolled using consent/assent forms which have a valid "IRB Approval" stamp unless using an electronic consent that doesn't accommodate use of an E-IRB stamp.] Prior to the end of this period, you will be sent a Continuation Review (CR)/Annual Administrative Review (AAR) request which must be completed and submitted to the Office of Research Integrity so that the protocol can be reviewed and approved for the next period.

In implementing the research activities, you are responsible for complying with IRB decisions, conditions and requirements. The research procedures should be implemented as approved in the IRB protocol. It is the principal investigator's responsibility to ensure any changes planned for the research are submitted for review and approval by the IRB prior to implementation. Protocol changes made without prior IRB approval to eliminate apparent hazards to the subject(s) should be reported in writing immediately to the IRB. Furthermore, discontinuing a study or completion of a study is considered a change in the protocol's status and therefore the IRB should be promptly notified in writing.

For information describing investigator responsibilities after obtaining IRB approval, download and read the document "[PI Guidance to Responsibilities, Qualifications, Records and Documentation of Human Subjects Research](#)" available in the online Office of Research Integrity's [IRB Survival Handbook](#). Additional information regarding IRB review, federal regulations, and institutional policies may be found through [ORI's web site](#). If you have questions, need additional information, or would like a paper copy of the above mentioned document, contact the Office of Research Integrity at 859-257-9428.

see blue.

405 Kinkead Hall | Lexington, KY 40506-0057 | P: 859-257-9428 | F: 859-257-8995 | www.research.uky.edu/ori/

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Eastern Association for the Surgery of Trauma
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EAST MULTICENTER STUDY

DATA COLLECTION TOOL

Multicenter Study: Cerebrovascular Antithrombotic Therapy in Trauma

Enrolling Center: _____

Enrolling Co-investigator: _____

Demographics / Injury Variables:

Site Specific ID: "UK1" _____

Sex:

Female ____ Male ____

Ethnicity:

Hispanic or Latino ____ NOT Hispanic or Latino ____ Unknown / Not Reported ____

Race:

American Indian/Alaska Native ____ Asian ____ Native Hawaiian or Other Pacific
Islander ____

Black or African American ____ White ____ More Than One Race ____ Unknown / Not
Reported ____

Age (years): _____

Height (cm): _____

Weight (kilograms): _____

BMI: _____

Any comorbid condition: _____

Injury Data:

Date of Hospital Arrival: _____ Arrival Time: _____

Date Antithrombotic Therapy was Begun: _____

Date of Hospital Discharge: _____

Mechanism of Injury:

Blunt _____ Penetrating _____

Abbreviated Injury Score - Head: _____

Abbreviated Injury Score - Face: _____

Abbreviated Injury Score - Neck: _____

Abbreviated Injury Score - Chest: _____

Abbreviated Injury Score - Abdomen: _____

Abbreviated Injury Score - Spine: _____

Abbreviated Injury Score - Extremity: _____

BCVI and Vitals:

BCVI Biffl Score: _____

BCVI Location:

Vertebral Artery _____ Carotid Artery _____

Level of Trauma Activation:

None _____ Partial _____ Full _____

GCS on Admission: _____

Systolic Blood Pressure on Admission: _____

Heart Rate on Admission: _____

Hospital Course:

Hospital Length of Stay: _____

ICU Length of Stay: _____

Anti-Thrombotic Therapy Start Date and Time: _____

Anti-Thrombotic Therapy:

Anti-Platelet Therapy ____ Systemic Anticoagulation ____

Type of Anti-Platelet Therapy:

Aspirin 81 mg ____

Aspirin 325 mg ____

Clopidogrel 75 mg ____

Aspirin 81 mg + Clopidogrel 75 mg ____

Aspirin 325 mg + Clopidogrel 75 mg ____

Other (specify) ____

Specific Anti-Platelet Medication and Dose: _____

Type of Systemic Anti-Coagulation:

Heparin (IV) ____

Enoxaparin ____

Apixaban ____

Rivaroxaban ____

Warfarin ____

Other (specify) ____

Systemic Anti-Coagulant Dose: _____

Partial Thromboplastin Time: _____

Anti-Xa Titer: _____

Prothrombin Time: _____

Outcome Data:

Discharge Location:

Home ____

Skilled nursing facility ____

Inpatient rehabilitation facility ____

Hospice ____

Against medical advice ____

Expired ____

Mortality Data:

Did this patient die in the hospital? No ____ Yes ____

Date of death: _____

What was the cause of death? _____

Stroke Data:

Did this patient have a stroke? No ____ Yes ____

Date of Stroke: _____ Time of Stroke: _____

Was stroke present on admission? No ____ Yes ____ Unknown ____

What was the nature of the stroke? _____

Complication Data:

Did this patient have a bleeding complication? No ____ Yes ____

Date of complication: _____ Time of Complication: _____

What was the nature of the complication?

Intracranial Hemorrhage ____

GI Hemorrhage ____

Solid Organ Hemorrhage ____

Intrabdominal Hemorrhage ____

Other ____

Please specify nature of hemorrhagic complication: _____

General Comments: _____

Imaging Studies:

Radiology Report: _____

Scan Date and Time: _____

Scan Type: CTA ____ MRA ____



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EAST Multicenter Study

DATA DICTIONARY

Cerebrovascular Antithrombotic Therapy in Trauma

– Data Dictionary

Data Entry Points and appropriate definitions / clarifications:

Demographics

Entry Space	Definition / Instructions
Site Specific ID "UK1"	Free text entry for unique site-specific identifier (e.g., "UK1").
Sex	Select patient's sex. Options include: Female; Male.
Ethnicity	Select patient's ethnicity. Options include: Hispanic or Latino; NOT Hispanic or Latino; Unknown / Not Reported.
Race	Check all that apply for patient's race. Options: American Indian / Alaska Native; Asian; Black or African American; Native Hawaiian or Other Pacific Islander; White; More Than One Race; Unknown / Not Reported.
Age (years)	Enter patient's age in years.
Height (cm)	Enter patient's height in centimeters.
Weight (kilograms)	Enter patient's weight in kilograms.
BMI	Calculated field: BMI, computed as $\text{round}((\text{weight} \times 10\,000)/(\text{height}^2), 1)$.
Any comorbid condition	Free text entry to specify any comorbid condition.

Injury Data – Arrival

Entry Space	Definition / Instructions
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Date of Hospital Arrival	Date of hospital arrival (YYYY-MM-DD).
Arrival Time	Time of hospital arrival (HH:MM).
Date Antithrombotic Therapy was Begun	Date antithrombotic therapy was initiated (YYYY-MM-DD).
Date of hospital discharge	Date of hospital discharge (YYYY-MM-DD).

Injury Data – Injury Characteristics

Entry Space	Definition / Instructions
Mechanism of Injury	Select mechanism of injury. Options: Blunt; Penetrating.
Abbreviated Injury Score – Head	Abbreviated Injury Score (AIS) for the head region.
Abbreviated Injury Score – Face	AIS for the face region.
Abbreviated Injury Score – Neck	AIS for the neck region.
Abbreviated Injury Score – Chest	AIS for the chest region.
Abbreviated Injury Score – Abdomen	AIS for the abdomen region.
Abbreviated Injury Score – Spine	AIS for the spine region.
Abbreviated Injury Score – Extremity	AIS for the extremity regions.

BCVI

Entry Space	Definition / Instructions
BCVI Biffl Score	Blunt cerebrovascular injury (BCVI) Biffl classification score.
BCVI Location	Select location of BCVI. Options: Vertebral Artery; Carotid Artery.
Level of Trauma Activation	Level of trauma activation for this patient. Options: None; Partial; Full.

Vitals

Entry Space	Definition / Instructions
GCS on Admission	Glasgow Coma Scale score on admission.
Systolic Blood Pressure on Admission	Systolic blood pressure at admission (mmHg).
Heart Rate on Admission	Heart rate at admission (beats per minute).

Hospital Course – Admission

Entry Space	Definition / Instructions
Hospital Length of Stay	Total number of consecutive days hospitalized at initial admission.
ICU Length of Stay	Number of days requiring ICU admission.

Hospital Course – Therapy

Entry Space	Definition / Instructions
Anti-Thrombotic Therapy Start Date and Time	Date and time antithrombotic therapy was started (YYYY-MM-DD HH:MM).
Antithrombotic Therapy	Select type of antithrombotic therapy. Options: Anti-Platelet Therapy; Systemic Anticoagulation.
What type of anti-platelet therapy was the patient on at admission?	Select antiplatelet therapy: Aspirin 81 mg; Aspirin 325 mg; Clopidogrel 75 mg; Aspirin 81 mg + Clopidogrel 75 mg; Other (specify).
What specific anti-platelet medication and dosage was the patient on at admission?	Free text entry for medication name and dosage.
Which Type of Systemic Anti-Coagulation was the Patient on at admission?	Select systemic anticoagulant: Heparin (IV); Enoxaparin; Apixaban; Warfarin; Dabigatran; Rivaroxaban; Edoxaban; Other.
Systemic Anti-Coagulant Dose	Free text entry for dose of systemic anticoagulant.
Partial Thromboplastin Time	Free text entry for PTT value.
Anti-Xa Titer	Free text entry for Anti-Xa value.
Prothrombin Time	Free text entry for PT value.

Outcome Data – Discharge

Entry Space	Definition / Instructions
Discharge Location	Select discharge location. Options: Home; Skilled nursing facility; Inpatient rehabilitation facility; Hospice; Against medical advice; Expired.

Outcome Data – Mortality Data

Entry Space	Definition / Instructions
Did this patient die in the hospital?	Select Yes or No.
Date of death	Date of death (YYYY-MM-DD).
What was the cause of death?	Free text entry for cause of death.

Outcome Data – Stroke Data

Entry Space	Definition / Instructions
Did this patient have a stroke?	Select Yes or No.
Date of Stroke	Date of stroke (YYYY-MM-DD).
Time of Stroke	Time of stroke onset (HH:MM).

Was stroke present on admission?	Select whether stroke was present on admission. Options: Yes; No; Unknown.
What was the nature of the stroke?	Free text entry for stroke nature.

Outcome Data – Complication Data

Entry Space	Definition / Instructions
Did this patient have a bleeding complication?	Select Yes or No.
Date of complication	Date of complication (YYYY-MM-DD).
Time of Complication	Time of complication (HH:MM).
What was the nature of the complication?	Select complication type: Intracranial Hemorrhage; GI Hemorrhage; Solid Organ Hemorrhage; Intra-abdominal Hemorrhage; Other.
Please specify as to the nature of the hemorrhagic complication.	Free text entry if “Other” selected.

General Comments

Entry Space	Definition / Instructions
Comments	Free text entry for any additional comments or clarifications.

Imaging Studies

Entry Space	Definition / Instructions
Radiology Report	Free text entry for radiology report content.
Scan Date and Time	Date and time of imaging scan (YYYY-MM-DD HH:MM).
Scan Type	Select imaging modality. Options include: CTA; MRA.