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FWA00001119

07/21/2022

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PI Department: COM Surgery Trauma Surgery

Protocol Number: 263318
Protocol Title: Effects of Core Body Temperature on Rotational Thromboelastometry (ROTEM) Results in Surgical Trauma Patients

NEW SUBMISSION APPROVAL, EXPEDITED

The Institutional Review Board approved this study on 07/21/2022, based on Title 45 CFR 46.110 and/or applicable UAMS IRB policies, using expedited review procedures under categories: [2].

This approval period runs from 07/21/2022 to 07/20/2023

The IRB determined the risk for adults who enter this study to be minimal.

The IRB waived the requirement for obtaining consent and/or parental permission.

The IRB waived the requirement for HIPAA Authorization for the PHI described in the submission.

Committee Notes/Comments:

The following documents were received:

- Revised protocol 07/13/22 (**Type:** Protocol)

If you have any questions, please contact an IRB administrator at 501-686-5667.

IMPORTANT!
Start your research on the right foot! Please call the Office of Research Compliance at 501-526-6270 for a New Investigation Consult and Education **(NICE)** review. **NICE** Reviews occur once study procedures and documents are in place but prior to the first subject being enrolled. Designed to provide essential feedback on your proposed study documentation and processes, **NICE** reviews are meant to educate investigators and their teams about what is needed to be in place to help ensure research compliance once the study begins participant enrollment. Schedule your **NICE** review today!

Click here to access study.

Data Collection:

Outline the data collection plan/tool succinctly:

All data collected will be stored in REDCap and de-identified prior to sharing with research team members or participating sites. REDCap-stored data will include and be categorized in the following manner: Demographics, Transfer Data, Admission Hospital Variables, Patient outcomes.

Demographics:

- age, gender, weight, height, ethnic group, race, blood type, anticoagulant usage

Transfer data:

- Transfer variables: method of transfer EMS/flight, transfer time
- Blood product and fluid usage
    - Given by transportation services vs. in OSH
    - Product used (WB, PRBC, FFP, Cryo, TXA, PCC)
    - Warmed vs. not warmed
    - Pre-hospital interventions
        - Cardiac arrest
        - Surgical intervention (describe)
    - Fluids given (volume of crystalloid)
        - Type of crystalloid (plasmalyte, LR, NS)

Injury Specifics:

- Date and time of injury (or approximate)
- Date and time of admission to participating hospital
- Mechanism of trauma:
    - Blunt
    - Burn
    - Penetrating
    - Combination of blunt and burn
    - Combination of blunt and penetrating
    - Combination of burn and penetrating
- ISS
- AIS (max for each)
    - Head
    - Face
    - Neck
    - Thorax
    - Abdomen
    - Spine
    - UE
    - LE

Admitting Hospital Variables:

- Laboratory data (closest to time of ROTEM/TEG): hematocrit, hemoglobin, platelet count, lactate, base deficit, fibrinogen, INR, PT, PTT, pH, Ionized Calcium level, potassium level, creatinine
- Thromboelastography (TEG)/(rapid TEG) or ROTEM
    - TEG, rTEG, ROTEM data to include hypothermic data and standard protocol data
    - Temperature at time of sample collection
    - Time viscoelastic monitoring performed
    - Number of ROTEM/TEGs performed
        - Results of additional tests
        - Time performed for additional tests
        - Location of testing (ED, OR, ICU)
        - Temperature at time of sample collection (or closest to)
- Clinical or hemodynamic measures (first obtained at admitting hospital): Glasgow Coma Scale, systolic BP, mean arterial pressure, heart rate, respiratory rate, tissue oxygen saturation, temperature
    - Time temperature obtained
    - Time of first **normothermic** temperature value
- Blood product, hemostatic adjuncts and fluids administered <u>in hospital PRIOR</u> to viscoelastic monitoring:
    - RBC, plasma, platelet, cryoprecipitate, tranexamic acid, prothrombin complex concentrates
        - Warmed Y/N
    - Fluid (type and volume)
        - Warmed Y/N
- Laboratory data (at time of initial resuscitation completion): hematocrit, hemoglobin, platelet count, lactate, base deficit, fibrinogen, INR, PT, PTT, pH, Calcium level, potassium level, creatinine
- Warming measures utilized:
    - Warm blankets/heat packs
    - Bair hugger/WarmAir
    - Intravenous warmed fluid administration
    - Warmed inta-abdominal irrigation
    - Warm bladder irrigation
    - Warmed, humidified oxygen
    - ECMO
- Surgical interventions performed (select all that apply):
    - Ex-lap with closure
    - Ex-lap with application temporary closure device
    - Cardiac repair
    - Anatomic pulmonary resection
    - Non-anatomic pulmonary resection (wedge, tractotomy)
    - Splenectomy

- R nephrectomy
- L nephrectomy
- Bladder repair
- SBR
- LBR
- Liver resection
- Hepatorraphy
- Amputation LE
- Amputation UE
- EVAR
- TEVAR
- Major vascular repair
  - Carotid system
  - Iliac system
- EVD/Bolt placement
- Craniotomy
- Craniectomy

Patient Comorbidities

- Pre-hospital cardiac arrest
- Advance directive limiting care
- Alcohol use disorder
- Angina Pectoris
- Anticoagulant therapy
- Attention deficit/Attention deficit hyperactivity disorder
- Bleeding disorder
- Cerebrovascular accidence (CVA)
- COPD
- Chronic renal failure
- Cirrhosis
- Congenital Anomalies
- Congestive heart failure
- Current smoker
- Currently receiving chemotherapy
- Dementia
- Diabetes Mellitus
- Disseminated cancer
- Functionally dependent health status
- Mental/personality disorders
- Hypertension
- Myocardial infarction
- Peripheral artery disease

- Pregnancy
- Prematurity
- Steroid use
- Substance use disorder

Patient Outcomes:

- Total blood product utilization in first 24 hours of hospital admission
- Total blood product utilization during hospital stay
- ICU LOS
- Hospital LOS
- Ventilator days
- ARDS (mild, moderate, severe)
- AKI
- DVT/PE
    - Location of DVT
- 28 day mortality
    - Y/N
    - Date/Time
- Primary cause of death
    - Cause of death will be categorized into hemorrhage, CNS injury, multiple organ failure, or other

Data Dictionary: Standard ROTEM Protocols May Mask Underlying Coagulopathy in Hypothermic Trauma Patients

GENERAL INFORMATION:

For questions or concerns regarding data entry, variable specifics, or general REDCap usage to include: access, entry, queries, or requesting your site specific data for internal usage, please contact Maraya Camazine at mcamazine@uams.edu

Each participating site will be assigned a site ID. These will be used in conjunction with chronological numeric progression to assign study IDs to patients. Study IDs will not be duplicated and only account for a single patient.

Example: Site ID 1, patient 1, will be entered as 01-01, patient 2 will be entered as 01-02

Please use this document to assist with recording data on study participants. For fields where data is not applicable, not recorded, or unknown, please enter a ".". This will assist with final data queries. Blank variables will be flagged for query and require responses prior to a record being termed complete.

Accessing UAMS REDCap:

- Website:
- All personnel entering data into the REDCap system will need their **own** username through UAMS
- Log in using the username assigned to you after application and selected password.
- You should see a series of tabs at the top of the page. Select the "My Projects" tab.
- Once on the "My Projects" tab, there is a table titled "My Projects". There should be a project named "Viscoelastic Monitoring in Hypothermic Trauma Patients" in this table. Click it.
- You are now in the "Viscoelastic Monitoring in Hypothermic Trauma Patients" Project. To begin data entry, use the dashboard on the left side of the screen.
- Click "Add/Edit Records".
- To enter a new patient, enter a new study ID in the corresponding box. To edit or continue a previously started patient, select the corresponding patient ID number from the drop down box. Make sure you complete each Data Collection Instrument for each patient.

Abbreviations:
AIS: Abbreviated Injury Score
AKI: Acute Kidney Injury
ARDS: Acute Respiratory Distress Syndrome
CFT: Clot Formation Time
CNS: Central Nervous System
CPR: Cardiopulmonary Resuscitation
CT: Clotting Time
DVT: Deep Vein Thrombosis

ECMO: Extracorporeal Membrane Oxygenation
EMS: Emergency Medical Services
EVAR: Endovascular Aortic Aneurysm Repair
EVD: External Ventricular Drain
FFP: Fresh Frozen Plasma
ICU: Intensive Care Unit
INR: International Noramlised Ratio
ISS: Injury Severity Score
K: K value (TEG)
LOS: Length of Stay
LY30: Lysis at 30 minutes
MA: Maximum Amplitude
MCF: Maximum Clot Formation
ML: Maximum Lysis
MTP: Massive Transfusion Protocol
OR: Operating Room
PCC: Prothrombin Complex Concentrates
PRBC: Packed Red Blood Cells
PT: Prothrombin Time
PTT: Partial Thromboplastin Time
R: Reaction Time (TEG)
ROTEM: Rotational Thromboelastometry
TEG: Thromboelastography
TEVAR: Thoracic Endovascular Aortic repair
TXA: Tranexamic acid

Inclusion Criteria:

- Age $\geq$ 18 years of age
- Temperature $\leq$ 35 Celsius (can be obtained by core, axillary, or thermal scanner)
- ROTEM or TEG is obtained as part of normal trauma workup

Special considerations:

- Patients on anticoagulants and antiplatelets **will be included in this study**, it is not an exclusion criteria

DATA COLLECTION:

Demographics:

- Age: age in years at time of encounter
- Gender: select either male or female as the biological sex of patient
- Race: patient identified race, if patient is unable to specify their race or expires prior to specifying, select unknown
- Weight: first recorded weight in kilograms of patient during encounter
- Height: first recorded height in centimeters of patient during encounter
- Blood type: laboratory determined ABO blood type
- Anticoagulant and antiplatelet usage:

    - Please select “Yes” if patient has active known anticoagulant usage prior to hospital visit
        - Select types of anticoagulants and antiplatelets
    - Please select “No” if patient denies anticoagulant usage prior to hospital visit
- Comorbidities: Please mark all comorbidities identified by patient or listed within the chart
    - Pre-hospital cardiac arrest
    - Advance directive limiting care
    - AIDS/HIV
    - Alcohol use disorder
    - Angina Pectoris
    - Anticoagulant therapy
    - Attention deficit/Attention deficit hyperactivity disorder
    - Bleeding disorder
    - Cerebrovascular accidence (CVA)
    - COPD
    - Chronic renal failure
    - Cirrhosis
    - Congenital Anomalies
    - Congestive heart failure
    - Current smoker
    - Currently receiving chemotherapy
    - Dementia
    - Diabetes Mellitus
    - Disseminated cancer
    - Functionally dependent health status
    - Mental/personality disorders
    - Hypertension
    - Myocardial infarction
    - Paraplegia or hemiplegia
    - Peripheral artery disease
    - Pregnancy
    - Prematurity
    - Steroid use
    - Substance use disorder

Transfer Data:

- Method of transfer: select if patient was transported to your hospital via ground emergency medical services, personal owned vehicle, or flight services
- Transfer duration: total time in minutes or best approximate time for total duration required to transfer patient from scene or outside hospital
    - **If multiple transfers were required, input transfer time from most immediate referring facility to yours**
- Products and fluids given by transport:
    - Administering entities (select all that apply):

        - EMS/Flight transport
        - Outside Hospital
    - Products given (select all that apply):
        - Whole blood: indicate if whole blood was given and enter number of units
        - Packed red blood cells: indicate if PRBCs were given and enter number of units
        - Fresh frozen plasma: indicate if FFP was given and enter number of units
        - Platelets: indicate if platelets were given and enter number of units
        - Cryoprecipitate: indicate if cryoprecipitate was given and enter number of units
        - Prothrombin complex concentrates: indicate if PCCs were given and enter number of units
        - Tranexamic acid: indicate if TXA was given and enter number of grams
        - Crystalloids: indicate if crystalloids were given and volume (mLs)
    - Were any products warmed prior to administration?
        - If "yes" please indicate which products were warmed
    - Pre-Hospital interventions:
        - Surgical intervention: in text box please describe all procedures performed in OR prior to transfer to your facility
        - Procedural interventions: please select all procedural interventions performed at outside facility or in the field prior to arrival at your institution
            - Chest tube insertion
            - Central venous access
            - Arterial access
            - Intubation
            - Cricothyroidotomy
            - Cardiac arrest requiring CPR

Injury Specific Data:

- Date and time of injury: record in MM/DD/YYYY HH:MM (in military 24 hour time)
- Date and time of admission to participating hospital: record in MM/DD/YYYY HH:MM (in military 24 hour time)
- Mechanism of trauma (select one):
    - Blunt
    - Burn
    - Penetrating
    - Combination of blunt and burn
    - Combination of blunt and penetrating
    - Combination of burn and penetrating
- Injury severity score: please enter ISS
- Abbreviated Injury Scale Score: Please enter highest AIS for all affected body regions. For areas not affected please input "."
    - Head
    - Face
    - Neck

- Thorax
- Abdomen
- Spine
- Upper extremity
- Lower extremity

Admitting Hospital Variables:

- Clinical or hemodynamic measures **(first set of values obtained by admitting hospital)**
  - Time vitals were obtained: enter HH:MM (please use military time)
  - Glasgow coma Scale
  - Systolic blood pressure: record in mmHg
  - Mean arterial pressure: record in mmHg
  - Heart rate: record in beats per minute
  - Respiratory rate: record in breaths per minute
  - Tissue oxygen saturation: record in percentage
  - Temperature: record in degrees Celsius
    - Please indicate method of obtaining temperature:
      - Core temperature
      - Axillary temperature
      - Temperature scanning device
- Warming measures utilized (select the box if patient received any of the following):
  - Warm blankets/heat packs
  - Bair hugger/WarmAir
  - Intravenous warmed fluid administration
  - Warmed intra-abdominal irrigation
  - Warm bladder irrigation
  - Warmed, humidified oxygen
  - ECMO
- Blood products and hemostatic agents administered **in hospital PRIOR** to viscoelastic monitoring:
  - Whole blood: indicate total number of units administered in hospital prior to obtaining viscoelastic assays. If none of this product was given, input "0"
  - Packed red blood cells: indicate total number of units administered in hospital prior to obtaining viscoelastic assays. If none of this product was given, input "0"
  - Fresh frozen plasma: indicate total number of units administered in hospital prior to obtaining viscoelastic assays. If none of this product was given, input "0"
  - Platelets: indicate total number of units administered in hospital prior to obtaining viscoelastic assays. If none of this product was given, input "0"
  - Cryoprecipitate: indicate total number of units administered in hospital prior to obtaining viscoelastic assays. If none of this product was given, input "0"
  - Prothrombin complex concentrates: indicate total number of units administered in hospital prior to obtaining viscoelastic assays. If none of this product was given, input "0"
  - Tranexamic acid: indicate total volume of TXA administered in hospital prior to obtaining viscoelastic assays. If none of this product was given, input "0"
    - Were any of the above products warmed prior to administration?

        - If "yes" select all that apply
- Viscoelastic monitoring data **(this will be the <u>first set</u> of TEG/ROTEMs):**
    - Temperature at time of sample collection: record in Celsius
    - Time of sample collection: record in HH:MM using 24 hour military time reporting
    - <u>For ROTEM Samples:</u>
        - **<u>Please record STANDARD protocol results first, separate section will populate for hypothermic protocol results to be entered</u>**
        - EXTEM:
            - CT: Record in seconds
            - CFT: Record in seconds
            - a: Record alpha value
            - A10: Record in mm
            - A20: Record in mm
            - MCF: Record in mm
            - ML: Record in percentages
        - INTEM:
            - CT: Record in seconds
            - CFT: Record in seconds
            - a: Record alpha value
            - A10: Record in mm
            - A20: Record in mm
            - MCF: Record in mm
            - ML: Record in percentages
        - FIBTEM:
            - CT: Record in seconds
            - CFT: Record in seconds
            - a: Record alpha value
            - A10: Record in mm
            - A20: Record in mm
            - MCF: Record in mm
            - ML: Record in percentages
    - For TEG Samples:
        - **<u>Please record STANDARD protocol results first, separate section will populate for hypothermic protocol results to be entered</u>**
        - R: Record in seconds
        - K: Record in seconds
        - a: Record alpha angle
        - MA: Record in mm
        - A10: Record in mm
        - A20: Record in mm
        - LY 30%: Record in percentage
- Laboratory data **(measures obtained closest to time of ROTEM/TEG):**
    - Hemoglobin: Record hemoglobin in g/dL
    - Hematocrit: Record hematocrit percentage

    - Platelet count: Record platelet count in 10^9/L
    - Calcium level: Record in mg/dL
    - Potassium level: Record in mmol/L
    - Creatinine: Record in mg/dL
    - pH: Record pH
    - Lactate: Record lactate in mmol/L
    - Base deficit: Record base deficit in mmol/L. Can be from arterial, capillary, or venous sites
    - Fibrinogen: Record fibrinogen in mg/dL
    - PT: Record PT in seconds
    - PTT: Record PTT in seconds
    - INR: Record INR
- Additional Viscoelastic monitoring data **(this will be all subsequently performed ROTEM/TEG):**
    - Temperature at time of sample collection: record in Celsius, may use closest recorded temperature to time of collection
    - Time of sample collection: record in HH:MM using 24 hour military time reporting
    - Input ROTEM/TEG variables as appropriate using methodology as above
- Time of first **normothermic** temperature values: record in MM/DD/YYYY HH:MM using 24 hour military time reporting
- Record first **normothermic** temperature value: record in Celsius
- Surgical interventions performed (select all that apply):
    - Exploratory laparotomy with closure
    - Exploratory laparotomy with application of temporary closure device
    - Cardiac repair
    - Anatomic pulmonary resection
    - Non-anatomic pulmonary resection (wedge, tractotomy)
    - Splenectomy
    - Nephrectomy
    - Bladder repair
    - Small bowel resection
    - Large bowel resection
    - Liver resection
    - Hepatorraphy
    - Amputation of lower extremity
    - Amputation upper extremity
    - EVAR
    - TEVAR
    - Major vascular repair: please indicate vessels repaired
    - EVD/Bolt placement
    - Craniotomy
    - Craniectomy

Patient Outcomes:

- Total blood product utilization in first 24 hours of hospital admission:

    - Whole blood: indicate total number of units administered in first 24 hours of care. If none of this product was given, input "0"
    - Packed red blood cells: indicate total number of units administered in first 24 hours of care. If none of this product was given, input "0"
    - Fresh frozen plasma: indicate total number of units administered in first 24 hours of care. If none of this product was given, input "0"
    - Platelets: indicate total number of units administered in first 24 hours of care. If none of this product was given, input "0"
    - Cryoprecipitate: indicate total number of units administered in first 24 hours of care. If none of this product was given, input "0"
    - Prothrombin complex concentrates: indicate total number of units administered in first 24 hours of care. If none of this product was given, input "0"
    - Tranexamic acid: indicate total volume of TXA administered in first 24 hours of care in grams. If none of this product was given, input "0"
- Total blood product utilization during hospital stay
    - Whole blood: indicate total number of units administered during hospitalization. If none of this product was given, input "0"
    - Packed red blood cells: indicate total number of units administered during hospitalization. If none of this product was given, input "0"
    - Fresh frozen plasma: indicate total number of units administered during hospitalization. If none of this product was given, input "0"
    - Platelets: indicate total number of units administered during hospitalization. If none of this product was given, input "0"
    - Cryoprecipitate: indicate total number of units administered during hospitalization. If none of this product was given, input "0"
    - Prothrombin complex concentrates: indicate total number of units administered during hospitalization. If none of this product was given, input "0"
    - Tranexamic acid: indicate total volume of TXA administered during hospitalization in grams. If none of this product was given, input "0"
- ICU LOS: enter ICU LOS rounded to nearest day
- Hospital LOS: enter hospital LOS rounded to nearest day
- Ventilator days: enter total number of days the patient utilized a ventilator rounded to nearest day
- ARDS (mild, moderate, severe): select "yes" if patient developed ARDS
    - ARDS requires the following:
        - Timing: within 1 week of known clinical insult o new or worsening respiratory symptoms
        - Chest imaging: bilateral opacities – not fully explained by effusions, lobar/lung collapse or nodules
        - Origin of edema: respiratory failure not fully explained by cardiac failure or fluid overload
        - Please also indicate severity:
            - **Mild:** 200 mmHg $\leq$ PaO2/FiO2 $\leq$ 300 mmHg with PEEP or CPAP $\geq$ 5 cm H2O
            - **Moderate:** 100 mmHg $\leq$ PaO2/FIO2 $\leq$ 200 mmHg with PEEP $\geq$ 5 cm H2O

- **Severe:** PaO2/FiO2 ≤ 100 mmHg with PEEP ≥ 5 cm H2O

- AKI: select "yes" if patient developed an AKI during hospital stay as defined by
  - AKI requires 1 of the following criteria:
    - Increase in serum creatinine by ≥ 0.3 mg/dl (≥ 26.5 umol/l) within 48 hours
    - Increase is serum creatinine by ≥ 1.5 times baseline
      - Baseline value is known or presumed in the last 7 days and should be determine prior to event
    - Urine volume < 0.5 ml/kg/hr for 6 hours
- DVT: select "yes" if patient developed a DVI
  - Location of DVT
- Pulmonary embolism: select "yes" if patient developed a pulmonary embolism
- 28 day mortality
  - If patient expired within 28 days of enrollment please select "Yes", if not select "No"
  - If patient expired, please also enter date and time of death in DD/MM/YYYY HH:MM format using 24 hour time reporting
- Primary cause of death
  - Cause of death will be categorized into hemorrhage, CNS injury, multiple organ failure, or other
    - Hemorrhage: uncontrolled bleeding leading to cardiac arrest, bleeding from organs/vessels not amenable to surgical intervention and not compatible with life
    - CNS injury: traumatic brain injury deemed non-survivable leading to withdrawal of care
    - Multiple organ failure: overwhelming sepsis leading to multisystem organ failure and death, destruction of enteric system not compatible with life, uncontrolled DIC leading to multisystem failure
    - Other: please type in events leading to death or proposed causes of death and coordinating site will assign a category