OHSU Emergency Medicine

Clinical Trials Newsletter

September 2024

Director's Corner

After a short break, we have a revamped clinical trials newsletter. We hope it better summarizes and captures your attention (with study spotlights) on all the amazing research happening in the Emergency Department and our collaborations with other departments. We also understand how tough our ED environment is, and appreciate your patience, resilience, and help in continuing to move the needle forward in research and clinical care. If you have any questions about any of the studies, please contact the principal investigator. Enjoy the last days of summer!

Bory Kea, MD, MCR, Director of Clinical Trials

New Study Spotlight

Amiodarone Concentration Evaluation in Cardiac Arrest Patients (ACE-CAP)
PI: Joshua Lupton, MD ***Coordinator:*** Dalton Wesemann

AstraZeneca REVERXal: A multinational observational longitudinal study to describe the patient characteristics, health care interventions, and health outcomes of patients with major bleedings in the presence of Factor Xa inhibitor treatment
PI: Bory Kea, MD ***Coordinator:*** Dalton Wesemann

Patterns Of Survivors' Recovery Trajectories in the ICECAP Trial (POST-ICECAP)
PI: Mo Daya, MD ***Coordinators:*** Dalton Wesemann, Jeff Smith

Real-World Examination of Naloxone for Drug Overdose Reversal (RENDOR)
PI: Jonathan Jui, MD ***Coordinator:*** Jeff Smith

VBI-S: A Phase III, Open Label, Randomized, Controlled Study of VBI-S in the Treatment of Hypovolemia in Patients with Septic Shock
PI: Akram Khan, MD ***Coordinator:*** PRISM Research Team

Trauma Resuscitation with Low-Titer Group O Whole Blood or Products (TROOP)
PI: Martin Schreiber, MD, Mitchell Sally, MD ***Coordinator:*** Austin Lerwick

Provide your input!

Early Amiodarone in Shockable Cardiac Arrest (Early-Amio) Study

The objective of Early-Amio is to test a new protocol to deliver amiodarone one-cycle earlier during out-of-hospital cardiac arrest due to a shockable initial rhythm. This study will be conducted under exception from informed consent and we are conducting community consultations.

Please complete this survey to provide your valuable input on the study.

PI: Josh Lupton **Coordinator:** Dalton Wesemann

Active Studies

Center for Policy & Research in Emergency Medicine (CPR-EM)

ACE-CAP	AF CDS	CRASHED
DOTS	ESCAPED	FAST EXAM
Fentalog	GUIDED HF	ICECAP
PediDOSE	P-ICECAP	POST-ICECAP
Proximal Risk	RENDOR	REVERXal
Solace	STRATIFY	

Pulmonary/Critical Care & PRISM Research Group

AIMS	CHILL	Direct Biologics	IVY-6
RESPIRATIO	STRIVE	VBI-S	

Trauma Research Group

BOOST-3	PACT	Prehospital Kcentra
TAP	TROOP	

Hey ED Providers!
Have you completed the AF CDS education survey?
Complete the following survey to be entered into a raffle!

Have a study you would like included in the next newsletter?
Email us! cprem@ohsu.edu

Center for Policy & Research in Emergency Medicine

SIREN Network Studies

ICECAP – Influence of Cooling Duration on Efficacy in Cardiac Arrest Patients

This study will enroll comatose adult survivors of out of hospital cardiac arrest that have already been rapidly cooled using a definitive temperature control method.
Launched: September 2020
Site: Portland Adventist ED
ICECAP PI: Daya, **ICECAP Co-I:** Julia Durrant *(OHSU)*, Miko Enomoto *(OHSU)*, Josh Lupton *(OHSU & Portland Adventist)*, Marwan Mouammar *(Portland Adventist)*, Matthew Neth *(Portland Adventist)*, William Spurlock *(Portland Adventist)*, **Coordinator:** Jeff Smith **Registered with ClinicalTrials.gov:** NCT 04217551
FDA IDE: William Meurer, G160072
Status: Enrolling; **Enrolled:** 68; **All site total:** 982
Contact: Jeff Smith, smitjeff@ohsu.edu

POST-ICECAP: Patterns Of Survivors' Recovery Trajectories in the ICECAP Trial

This study is an ancillary study to the ICECAP study which focuses on a new equitable science of out of hospital cardiac arrest (OHCA) survivorship itself, seeking empirically derived targets for preserving or restoring recovery. The study aims to describe recovery (functional outcome [primary], Cognition, and HRQoL outcomes [secondary]) in a large, well-characterized, racially/ethnically diverse, representative cohort of US OHCA patients.
Launched: July 2024
Site: Portland Adventist ED
PI: Mo Daya, **Co-I:** Josh Lupton, Matt Neth
Coordinators: Dalton Wesemann, Jeff Smith
NIH Project Number: 1R01NS127959-01A1
Status: Enrolling; **Enrolled:** 1; **All site total:** 24
Contact: Dalton Wesemann, wesemann@ohsu.edu; Jeff Smith, smitjeff@ohsu.edu

P-ICECAP – Pediatric Influence of Cooling Duration on Efficacy in Cardiac Arrest Patients

This study is a multicenter, randomized, adaptive allocation clinical trial to identify the optimal duration of induced hypothermia for neuroprotection in comatose survivors of cardiac arrest.
Launched: October 2022
Site: Doernbecher Children's Hospital
PI: Serena Kelly, **Co-I:** Aileen Kirby, Cydni Williams, Beech Burns, Mo Daya, Bory Kea **Coordinator:** Jeff Smith
Registered with ClinicalTrials.gov: NCT05376267
FDA IDE: William Meurer, G210126
Status: Enrolling; **Enrolled:** 6; **All site total:** 199
Contact: Jeff Smith, smitjeff@ohsu.edu

Amiodarone Concentration Evaluation in Cardiac Arrest Patients (ACE-CAP)

The objective of ACE-CAP is to evaluate serum amiodarone concentrations among cardiac arrest patients transported by EMS to explore differences in bioavailability based on route and time of administration. This study is conducted at Adventist and will obtain blood from cardiac arrest patients on arrival to the hospital if they received amiodarone from EMS.
Launched: August 26, 2024

PI: Joshua Lupton; **Study Coordinator:** Dalton Wesemann
Status: Enrolling
Contact: Joshua Lupton, lupton@ohsu.edu; Dalton Wesemann, wesemann@ohsu.edu

Atrial Fibrillation (AF) Clinical Decision Support (CDS) Tool

A stepped-wedge clinical trial of an electronic clinical decision support tool to improve stroke prevention in patients with atrial fibrillation. Patients and providers will be recruited for qualitative interviews at 3 sites (OHSU, AHP, HMC).

- **Launched Step 1 (Link Out): OHSU – January 11, 2022; HMC – April 4, 2022**
- **Relaunched Step 1 after Epic transition: AHP – April 20, 2023**
- **Launched Step 2 (Link + BPA): OHSU – March 1, 2023; HMC - August 1, 2023; AHP- August 13, 2024**
- **Launched Step 3 (Link + BPA w/FHIR integration): OHSU – August 13, 2024**

View the <2 minute Phase 2 and Phase 3 education videos here!

PI: Bory Kea; **Study Coordinator:** Maja Strusinska-Thayer
Inclusion: >18 years, OAC naïve
Status: Enrolling
Enrolled: Quantitative – 807; Qualitative – 17 patients, 18 providers
Contact: Maja Strusinska-Thayer, strusins@ohsu.edu

Automated Ultrasound Image Analysis of the Abdominal FAST Exam

Purpose of this study is to attain a library positive and negative abdominal ultrasound images of the standard Focused Assessment with Sonography for Trauma (FAST) imaging protocol, which can be subsequently annotated to train a machine learning algorithm.
Launched: October 13, 2021

Sites: OHSU, Medstar, Brook Army Medical Center, Tripler Army Medical Center, Womack Army Medical Center
PI: Nikolai Schnittke; **Coordinators:** Samantha Underwood and Michael Fleming
Inclusion: Adults ED trauma patients who either have a positive FAST exam performed and saved by the clinical team, or have a CT scan of the abdomen/pelvis performed as part of the trauma workup, with follow-up research FAST performed by the study team. Non-trauma patients with peritoneal fluid are also eligible for a research FAST exam performed by the study team.
Exclusion: Skin disease and/or wounds that would preclude transducer placement, prisoners.
Status: Enrolling
Contact: Nikolai Schnittke, schnittk@ohsu.edu

CRASHED: Cause of RASHes in the Emergency Department

Subtitle: Examining the Prevalence, Clinical Characteristics, and Treatment of Mpox in U.S. Emergency Departments Participating in EMERGEncy ID NET

The CDC Sponsored Emergency ID Network has collaborated with the investigators at CDC to deploy a 6 month national emergency department surveillance project for mPOX. The study is looking to describe Mpox prevalence in the ED population. The CRISP Team will assist in identification of potential study patients.
Launched: June 2023
PI: Jonathan Jui, MD; **Coordinator:** Mastura Wahedi
Inclusion: Patients (≥ 3 months old) with a rash of interest.(Essentially it is similar to a herpes zoster or varicella rash).
Status: Active.
Contact: Mastura Wahedi, wahedi@ohsu.edu

DOTS- Drug Overdose Toxico-Surveillance

DOTS is a multi-center project looking to identify illicit drugs in our community (as well as nationwide) and learn more about patterns of drug use. Illicit drugs will be identified in blood and the subject will answer questions about drug use in a structured interview.
Launched: April 2023
End date: September 30, 2024
Sites: 17 sites around the US
PI: Rob Hendrickson, MD; **Coordinator:** Jeff Smith
Inclusion: Subjects with toxicity from opioids, stimulants, or unknown illicit drugs who are older than 12 years.
Exclusion: if symptoms are more likely due to a non-drug toxicity.
Status: Enrolling; **Enrolled:** 75; **All site total:** 880
Contact: Rob Hendrickson, hendriro@ohsu.edu; Jeff Smith, smitjeff@ohsu.edu

ESCAPED- Emerging Staphylococcus aureus Resistance and Current Antimicrobial Patterns in Emergency Departments

ESCAPED is a multicenter, prospective, observational project through the CDC sponsored EMERGEncy ID Network aimed at describing antimicrobial resistance of S. aureus and prescribing patterns for the management of purulent skin and soft tissue infections (SSTIs) in an emergency department (ED) setting.
Launched: August 27, 2024
PI: Jonathan Jui; **Coordinator:** Nick Patrick
Inclusion: Skin/soft tissue infection, all ages
Status: Active.
Contact: Nick Patrick, patricni@ohsu.edu

Learn more about ESCAPED here!

Exposure to Suicide-Related Media and Suicide Risk (Proximal risk)

The study hopes to identify risk factors that contribute to suicidal ideation and/or attempts in adolescents and adults. We aim to better understand how exposure and perceptions about suicide relate to suicidal severity in youth. The CRISP Team will be identifying all patients (≥18 - ≤89 years) who are presenting to the ED without active SI, SA or self-harm. These patients will be enrolled in the control group of this study. The team will identify patients on the trackboard who have a complaint unrelated to SI, SA or self-harm. 100 subjects will be enrolled.
Launched: August 19th, 2024
PIs: Jason Chen, David Sheridan; **Coordinator:** Brandon Roth
Status: Active.
Contact: Jason Chen, chenjaso@ohsu.edu; Brandon Roth, rothbr@ohsu.edu

Implementation of a Self-Care Plan for Patients with Acute Heart Failure Discharged from the ED (GUIDED-HF)

GUIDED-HF is a multi-site project with implementation of a self-care plan for acute heart failure (HF) at OHSU and Hillsboro Medical Center. This project aims to provide self-care coaching (x3 virtual visits) for patients discharged from the Emergency Department (ED) with HF.
Launched: February 1, 2022
Sites: OHSU & HMC
PI: Bory Kea; **Study Coordinator:** Dalton Wesemann
Inclusion: Diagnosed with HF and/or received loop diuretics in ED.
Status: Enrolling; **Enrolled:** 77
Contact: Dalton Wesemann, wesemann@ohsu.edu

Pediatric Dose Optimization for Seizures in EMS (PediDOSE)

This study is a multi-center, stepped wedge trial of midazolam dosing for seizures in pediatric patients in the Emergency Medical Services (EMS) setting.
It randomizes the timing of each of the participating EMS agencies at 20 different sites to switch from conventional, weight-based dosing to standardized, age-based dosing so that every EMS agency switches from conventional to standardized dosing over a 4-year enrollment period in this 5-year study. The primary outcome is seizing on ED arrival measured by the Ceribell Device. Federal exception from informed consent (EFIC) procedures will be used for enrollment.
Launched: November 2022
PI: Matthew Hansen, **Coordinator:** Nick Patrick
Inclusion: Patient is Age ≥ 6 months to ≤ 13 years AND had a paramedic-witnessed seizure AND Require transport to any hospital; Ceribell Placement on patients age ≥ 2 years.
Exclusion: Patient has a prior history of a benzodiazepine allergy; OR has known or presumed pregnancy; OR Has severe growth restriction based on the paramedic's assessment.
Status: Enrolling; **Enrolled:** 101; **All site total:** 2,804
Contact: cprem@ohsu.edu, **24-hour line:** 503-494-1777

Predicting medical consequences of novel fentanyl analog overdose using the Toxicology Investigators Consortium (ToxIC)

Purpose of this multi-center study is molecular identification and quantitation of fentanyl analogues (fentalogs) in a prospective cohort of 1300 Emergency Department (ED) patients with opioid overdose (OD) from the established ToxIC hospital network. The number of subjects to be enrolled at each ToxIC site is approximately between 25-100. As an Exploratory Sub-Aim, we will characterize psychostimulant drug co-ingestions with fentalogs (e.g. synthetic cannabinoids, cocaine, cathinones, etc.) to provide confirmatory identification and quantitation.
Launched: November 2020
PI: Adrienne Hughes
Inclusion: ED patient Opioid OD. Availability of waste blood or urine specimens for analysis.
Exclusion: Age < 18 years. Non-toxicological diagnosis. Prisoners. Trauma/Burns.
Status: Enrolling; Enrolled: 110
Contact: Adrienne Hughes, hughesad@ohsu.edu

Please use "poisoning by opioids" in your impression for all opioid overdoses.

Real-World Examination of Naloxone for Drug Overdose Reversal (RENDOR)

The purpose of the Toxicology Investigators Consortium (ToxIC) Real-World Examination of Naloxone for Drug Overdose Reversal (RENDOR) project is to assess the optimal amount of naloxone needed to reverse the effects of ultrapotent opioids and opioids involved in polydrug overdose including overdose of fentanyl and xylazine. RENDOR seeks to examine the pre-hospital administration of opioid antagonists (naloxone and/or nalmefene) in a real-world setting by utilizing the RENDOR prospective data collection tool for opioid antagonists administered before and after EMS arrival.
Launched: June 26, 2024
PI: Jonathan Jui, **Coordinator:** Jeff Smith
Status: Active
Contact: Jeff Smith, smitjeff@ohsu.edu

AstraZeneca REVERXal: A multinational observational longitudinal study to describe the patient characteristics, health care interventions, and health outcomes of patients with major bleedings in the presence of Factor Xa inhibitor treatment

REVERXaL study aims to increase the understanding of the patient characteristics, bleeding presentation, health care interventions provided, and the clinical as well as self-reported health outcomes of patients with major bleeding in the presence of Factor Xa inhibitor treatment. The generation of insight on treatment approaches and associated outcomes in hospitalized patients with Factor Xa inhibitor-related major bleeds may inform clinical guidelines, health system decision making and streamline treatment pathways in this population.
Launched: August 20, 2024
PI: Bory Kea, **Coordinator:** Dalton Wesemann
Registered with ClinicalTrials.gov: NCT06147830
Status: Enrolling
Contact: Dalton Wesemann, wesemann@ohsu.edu

Solace: Wearable Technology to Detect Physiologic Parameters in Suicidal Adolescents

The objective of this study is to evaluate various physiologic biosignals that could be associated with suicidality in adolescent patients. Patients presenting to the ED aged 13-17 with acute suicidal thoughts or attempt are enrolled if they provide assent/consent. The study protocol involves wearing a smartwatch and undergoing Ecologic Momentary Assessment (EMA). The EMA pings them 4x a day with validated suicidal scores. Using machine learning the goal is to predict the validated suicidal metrics with physiologic signals.
Launched: January 2023
PI: David Sheridan, MD, MCR; **Coordinator:** Dalton Wesemann
Status: Ongoing in the OHSU ED and Unity Inpatient Adolescent Psychiatric Unit
Contact: Dalton Wesemann, wesemann@ohsu.edu

Tailored Dissemination and Implementation of Emergency Care Clinical Decision Support to Improve Emergency Department Disposition (STRATIFY)

STRATIFY is a study on the development and dissemination/implementation of a clinical decision support tool for heart failure risk stratification and disposition. This project aims to examine ED workflow at OHSU and Hillsboro Medical Center (HMC) to determine how to best integrate it into a clinical decision support (CDS) tool for patient and provider shared-decision making, specifically for acute heart failure patients.

The STRATIFY tool went live at OHSU/HMC on 7/31/2024!

PI: Bory Kea; **Study Coordinator:** Maja Strusinska-Thayer
Status: Active
Contact: Maja Strusinska-Thayer, strusins@ohsu.edu

View the <2 minute STRATIFY video here!

Pulmonary/Critical Care & PRISM Research Group

Assessment of Implementation of Methods in Sepsis and Respiratory Failure (AIMS)

The Assessment of Implementation of Methods in Sepsis and Respiratory Failure (AIMS) study seeks to determine the safest and most effective approach to sepsis intervention using the evidence-based Surviving Sepsis Campaign guidelines. The goal of the AIMS study is to determine whether the Hour-1 or 3-Hour Bundle is most effective when implemented in emergency departments.

Launched: January 2023 **Status:** Ongoing
PI: Terri Hough, MD
Inclusion: All suspected sepsis patients
Status: Active
Contact: Scott Sherry, sherrys@ohsu.edu; Caitlyn Hickey, hickeyc@ohsu.edu

Click here to learn more about AIMS and the Sepsis Program!

CHILL: Cooling to Help Injured Lungs (CHILL) Phase IIB Randomized Control Trial of Therapeutic Hypothermia in Patients with ARDS

To test the hypothesis that early treatment with therapeutic hypothermia (TH) and neuromuscular blockade (NMB), to prevent compensatory shivering, will be beneficial for patients with acute respiratory distress.

Launched: June 2024 **Status:** Active, **Enrolled:** 0

PI: Akram Khan, MD; **Coordinators:** PRISM Research Team
Inclusion: Receiving mechanically ventilation via endotracheal tube (ETT) with PaO2/FiO2 ratio ≤ 200 mmHg; PEEP ≥ 8 cm H2O; patients aged 18-75; hospitalized for ARDS
Exclusion: missed moderate to severe ARDS window (>72hrs); significant, active bleeding; skin process that precludes cooling device; active hematologic malignancy; not likely to remain intubated for ≥ 48 hours
Contacts: Akram Khan, khana@ohsu.edu (page 15351), Genesis Briceno, parra@ohsu.edu (page 11912), Edvinas Pocius, pocius@ohsu.edu (page 11912) Vocera "MICU Research"

Learn more about CHILL here!

Direct Biologics stem cell: Bone Marrow Mesenchymal Stem Cell Derived Extracellular Vesicles for Hospitalized Patients with Moderate-to-Severe ARDS: A Phase III Clinical Trial

The objective of this study is to evaluate the safety and efficacy of IV administration of bone marrow mesenchymal stem cell derived from extracellular vesicles, ExoFlo, versus placebo for the treatment of hospitalized patients with moderate-to-severe ARDS.

Launched: November 2023 **Status:** Ongoing

PI: Akram Khan, MD; **Coordinator**: PRISM Research Team
Inclusion: Meets the established Berlin criteria of moderate-to-severe ARDS (chest imaging with bilateral opacities, PaO2/FiO2 <= 200mmHg)
Exclusion: ALT or AST >8x ULN, history of cirrhosis, DNR order, Moribund
Status: Enrolling; Enrolled: 4
Contact: Akram Khan, khana@ohsu.edu (page 15351); Jose Pena, penaj@ohsu.edu (page 11912); Vocera "MICU RESEARCH"

IVY-6: Influenza and Other Viruses in the Acutely Ill

Assessing the clinical validity of SARS-CoV-2 RT-PCR results and vaccine effectiveness.

Launched: September 2023 **Status:** Ongoing
Sites: OHSU & Vanderbilt University Medical Center
PI: Akram Khan, MD; **Coordinators:** PRISM Research Team
Inclusion: Acute symptom onset within 14 days of admission; positive or negative SARSCoV-2, influenza, or RSV test after onset of symptoms; COVID positive for cohort 1, COVID negative for cohort 2.
Exclusion: test > 14 days of onset of symptoms, previously enrolled in surveillance program.
Status: Active, Enrolled: 291
Contact: Akram Khan, khana@ohsu.edu (page 15351); Edvinas Pocius, pocius@ohsu.edu (page 11912); vocera "MICU RESEARCH"

DOMPE REP0122 ARDS: Phase 2. Proof-of-concept, randomized, double-blinded, placebo-controlled, multicenter study to assess efficacy and safety of reparixin as add-on therapy to standard of care in adult patients with Acute Respiratory Distress Syndrome (RESPIRATIO).

To characterize the efficacy of reparixin in ameliorating lung injury and systemic inflammation and expediting clinical recovery and liberation from mechanical ventilation in adult patients with moderate to severe ARDS, and to characterize the pharmacokinetics (PK) of reparixin in the same population of acutely ill pts enrolled in the study.

Launched: March 2023
PI: Akram Khan, MD; **Coordinators:** PRISM Research Team
Inclusion: mechanically ventilated pts with PaO2/FiO2 RATIO ≤200 in the presence of PEEP of ≥ 5cm H20, ≤ 48hrs of fulfilling ARDS criteria, ≤ 7 days from hospital admission.
Exclusion: eGFR < 30mL/min or hepatic, discharged.
Status: Active, Enrolled: 9
Contact: Akram Khan, khana@ohsu.edu (page 15351); Genesis Briceno, parra@ohsu.edu (page 11912); vocera "MICU RESEARCH"

STRIVE: Strategies and Treatments for Respiratory Infections & Amp; Viral Emergencies; Immune Modulation Strategy

To determine whether intensification of immune modulation (IM) early in the course of the respiratory disease (while patients are on low flow oxygen) with Abatacept (active arm) combined with standard of care (SOC) improves recovery compared with placebo + SOC (placebo arm).

Launched: July 2024

PI: Akram Khan, MD; **Coordinators:** PRISM Research Team
Status: Active, **Enrolled:** 4
Inclusion: confirmation of SARS-CoV2 infection by nucleic acid test (NAT) or equivalent non-NAT test (requiring hospitalization); evidence of Covid-19 pneumonia (PNA) defined by receiving supplemental low flow oxygen; currently planned to receive on IM drug (NOT abatacept)
Exclusion: oxygen requirement of 10 L/min or more of low flow oxygen; received more than one baseline IM for treatment of the current Covid-19 infection at the time of trial enrollment; neutropenia and/or lymphopenia; received any live vaccine within 3 months before screening
Contacts: Akram Khan, khana@ohsu.edu (page 15351)

VBI-S: A Phase III, Open Label, Randomized, Controlled Study of VBI-S in the Treatment of Hypovolemia in Patients with Septic Shock

To evaluate the safety and efficacy of VBI-S (phospholipid nanoparticle-based fluid) in elevating blood pressure of septic shock patients with absolute or relative hypovolemia.

Launched: August 2024

PI: Akram Khan, MD; **Coordinators:** PRISM Research Team
Status: Active, **Enrolled:** 0
Inclusion: Sepsis diagnosis; Mean BP < 65 mmHg that is unresponsive to fluids, SOFA score ≥ 5
Exclusion: acute coronary syndrome; emergency major surgery; diagnosis of acute Hep B or C; patients with a ventricular assist device; hematologic or coagulation disorders
Contacts: Akram Khan, khana@ohsu.edu (page 15351); Genesis Briceno, parra@ohsu.edu (page 11912); Edvinas Pocius, pocius@ohsu.edu (page 11912); Vocera "MICU Research"

Learn more about VBI-S here!

Trauma Research Group

BOOST-3 Brain Oxygen Optimization in Severe TBI Phase-3 Trial (a SIREN Network study)

BOOST 3 is a trial run through the nationwide SIREN Network. This study is comparing two strategies currently used for monitoring and treating patients with severe traumatic brain injury in the ICU. BOOST 3 allows for EFIC (Exception from Informed Consent) if an LAR is not present (within 6 hours).

Launched: March 16, 2020

BOOST-3 PI: David Zonies, **SIREN PI:** Daya, **Coordinator:** Austin Lerwick (TRG)

Registered with ClinicalTrials.gov: NCT03754114

Status: Enrolling; **Enrolled:** OHSU: 44; **All site total:** 666

Contact: Austin Lerwick, lerwick@ohsu.edu

BOOST-3 Sub-studies

BIO-BOOST: Biomarkers in the Brain Oxygen Optimization in Severe Traumatic Brain Injury Trial

Aims to quantify the effect of total brain tissue hypoxia exposure on brain injury using biofluid-based biomarkers of brain injury

ELECTRO-BOOST: Electroencephalography for cerebral trauma recovery and oxygenation

An observational cohort study evaluating the relationship between established biomarkers of metabolic demand (PbtO2), EEG abnormalities, clinical outcome, and treatment, seeking to identify dynamic EEG biomarkers of secondary injury that will enable future clinical trials seeking to improve functional outcomes for TBI patients.

PACT- Prehospital Airway Control Trial

PACT is an open-label, multi-site, stepped wedge randomized trial comparing a standard strategy of airway management with a strategy of first attempt with supraglottic airway (SGA) for trauma patients in a prehospital setting. The primary outcome is 24-hour mortality. It is assessed 24 hours after hospital arrival. Eight local agencies in the Clackamas and Washington counties are participating including AMR Clackamas, Clackamas County Fire District 1, Lake Oswego Fire, Molalla Fire, Canby Fire, Tualatin Valley Fire & Rescue, Hillsboro Fire & Rescue, and AMR Washington.

Launched: April 1, 2021

PI: Mo Daya, **Co-I:** Marty Schreiber **Coordinator:** Nancy Le, Laura Nguyen

Inclusion: Trauma requiring advanced airway management. Indicators of the need for advanced airway management include: a) GCS < 8, b) SpO2 < 90 despite supplemental oxygen, c) ETCO2 > 60 despite supplemental ventilation, or d) provider discretion. Transport to LITES Trauma Center – OHSU ONLY.

Exclusion: <15 years of age, pregnant, prisoner, initial advanced airway attempted by a non-PACT agency, in cardiac arrest without ROSC at time of intervention, caustic substance ingestion, airway burns, objection to enrollment voiced by subject or family members at the scene

Status: Enrolling; **Enrolled:** 156; **All Site total:** 1549

Contact: Nancy Le, lena@ohsu.edu

****OHSU Team- please remember to document: (1) Date & Time of Airway Exchange and (2) Reason for Airway Exchange (hypoxia, inadequate ventilation, etc).****

Prehospital Kcentra

A multicenter, pre-hospital pilot trial to determine the feasibility and safety of Kcentra administration for the early treatment of patients with traumatic shock, compared to placebo, in the field. Study treatment will be administered by select participating EMS agencies prior to ED arrival for eligible patients. This study will be conducted under EFIC (Exception from Informed Consent).

Launched: March 2021 **Sites:** OHSU and Seattle

PI: Schreiber and Philbert Van, MD; **Coordinators:** Austin Lerwick and Echo Meyers

Registered with ClinicalTrials.gov: NCT04019015

FDA IND: Martin Schreiber, 18153

Inclusion: 18 years and older, SBP <70 or no palpable pulse, suspicion of hemorrhagic shock, transport to participating hospital

Status: Active

Contact: Coordinators @trauma pager 11502 (for 24/7 coverage); Austin Lerwick, lerwick@ohsu.edu ; Echo Meyers, meyersec@ohsu.edu

Trauma and PCC Study (TAP)

The primary objective of the TAP study is to assess the efficacy of a single IV infusion of Kcentra on all-cause mortality at 6hrs after randomization (IP vs. Placebo) in subjects who have traumatic injury with no known anticoagulation treatment, and with confirmed or suspected acute major bleeding and/or predicted to receive a large volume blood product transfusion. Study treatment will be administered within 90 minutes of ED arrival for eligible patients. This study will be conducted under EFIC (Exception from Informed Consent).

Launched: November 19, 2023

PI: Martin Schreiber, MD and Philbert Van, MD; **Coordinators:** Echo Meyers and Austin Lerwick

Inclusion: Patients (≥ 15 years old) with a traumatic injury with confirmed or suspected acute major bleeding.

Status: Active.

Contact: Coordinators @trauma pager 11502 (for 24/7 coverage); Austin Lerwick, lerwick@ohsu.edu ; Echo Meyers, meyersec@ohsu.edu

Trauma Resuscitation with Low-Titer Group O Whole Blood or Products (TROOP).

The purpose of this study is to determine whether trauma patients requiring massive transfusion protocol activation for resuscitation do better after receiving only whole blood or only blood component products (red cells, platelets, plasma, cryoprecipitate). This study will be conducted under EFIC (Exception from Informed Consent).

Launched: December 2023

PI: Martin Schreiber, MD and Mitchell Sally, MD; **Coordinator:** Austin Lerwick

Registered with ClinicalTrials.gov: NCT05638581

Inclusion: Patients (≥ 15 years old) with a traumatic injury with confirmed or suspected acute major bleeding requiring MTP activation.

Status: Active

Contact: Coordinators @trauma pager 11502 (for 24/7 coverage); Austin Lerwick, lerwick@ohsu.edu