November 2021 Update on ED Clinical Trials

On the eve of our second pandemic Thanksgiving, thank you for all that *you* do for this department, your community, and friends and family. You are the heart and soul of this place. In the new year, we expect research activities to normalized (back to level 0--pre-pandemic level). As always, we welcome feedback and your involvement to ensure high-quality studies that integrate into our clinical workflow. Happy Thanksgiving.
–Bory Kea, MD, MCR, Director of Clinical Trials

For the interested reader, more details on the below research studies can be found at: http://www.ohsu.edu/cprem


COVID-19 STUDIES

- BinaxNOW
- Covid PreVent Trial (on hold)
- ACTIV-3 (TICO)
- ACTIV-4a (AC-INPT)
- COV-BARRIER

ACTIVE STUDIES

- AF CDS tool
- Beckman HF
- PACT
- KCENTRA
- Fentalog (ToxIC) (on hold)
- ICECAP
- BOOST-3
- HydraSense
- CLOVERS
- SAVE-O2

OHSU & ADVENTIST STUDIES

- BinaxNOW

COVID-19 STUDIES

Clinical Evaluation of the BinaxNOW® COVID-19 Antigen (Ag) Card
Objective: To estimate the clinical sensitivity and specificity of the BinaxNOW® COVID-19 Ag card against the reference method, Abbott RealTime SARS-CoV-2, in patients suspected of COVID-19 infection by *any* healthcare provider (RN, NP, PA, *or* MD) using nasal swabs. Staff will collect 2 nasal swabs from each subject. Swabs will be shipped to the Sponsor's central laboratory for reference testing.

Launched: August 2020 Sites: OHSU & Adventist

Study coordinators, Nancy & Joy, will check with clinical staff on suspected COVID-19 patients (there is no time limit on symptom duration) between Monday – Friday from 9:00-4:00 PM.

- **PI**: Bory Kea; **Coordinator**: Nancy Le
- **Inclusion**: Subject is suspected of COVID-19 infection by a healthcare provider.
- **Exclusion**: Subjects with active nose bleeds or acute facial injuries/trauma, currently enrolled in a study to evaluate an investigational drug, already participated in this study, unable/unwilling to provide informed consent, vulnerable populations (prisoners and pregnant woman).
- **Status**: Enrolling; **Enrolled: 283**
- **Contact:** Nancy Le, Clinical Research Coordinator: lena@ohsu.edu

Covid PreVent Trial

Purpose: Evaluating a single treatment of very low dose thoracic radiation in patients with s/sx of severe COVID, but prior to intubation, to determine whether intubation can be avoided. Can be on other trials, get normal meds.

- **PI:** Ravi Chandra, Radiation Medicine
- **Inclusion:** >50 yo, s/sx severe COVID (fever, tachypnea, oxygen requirement), hospitalized and sx for less than 9 days
- **Exclusion:** Mechanical ventilation, prior RT or intrinsic pulmonary disease, CHF exacerbation within 6 months
- **Status:** On hold
- **Contact:** Ravi Chandra, chandrav@ohsu.edu

ACTIV-3 (Therapeutics for Inpatients with COVID-19 [TICO])

A platform designed for testing therapeutic monoclonal antibody agents for adults hospitalized for COVID-19

Launched: August 4, 2020
Study Duration: July 2022

- **PI**: Akram Khan, MD ; **Coordinators**: PRISM Research Team
- **Inclusion**: > 18 yo, COVID + and symptomatic (< 12 days)
- **Exclusion**: received convalescent plasma, serious condition(s) present at enrollment (i.e. stroke, meningitis, encephalitis, congestive heart failure, DVT or PE)
- **Status**: ACTIVE, **Enrolled: 11**
- **Contact**: Akram Khan, khana@ohsu.edu ; Olivia Krol, krolo@ohsu.edu ; page 11912

ACTIV-4a (Antithrombotic Strategies in Hospitalized Adults with COVID-19 [AC-INPT])

Evaluating the effects of combining a P2Y12 inhibitor with anticoagulants for adults hospitalized for moderate to severe COVID-19. This is a continuation of the ACTIV-4 study, which evaluated prophylactic vs. therapeutic anticoagulation in adults hospitalized with COVID-19.

Launched: September 4, 2020
Study Duration: December 2021

- **PI:** Akram Khan, MD ; **Coordinators**: PRISM Research Team
- **Inclusion:** > 18 yo., COVID + and symptomatic, expected to require hospitalization for > 72 hours
- **Exclusion:** comfort care, ICU level of care (including high flow), ventilated, pregnant, low platelet or hemoglobin counts, contraindication to anticoagulation (i.e. recent stroke, bleeding disorder)
- **Status:** ACTIVE, **Enrolled**: **20**
- **Contact**: Akram Khan, khana@ohsu.edu ; Olivia Krol, krolo@ohsu.edu ; page 11912

A Study of Baricitinib (LY3009104) in Participants With COVID-19 (COV-BARRIER)
A randomized placebo-controlled trial of Barcitinib in the treatment of patients with COVID 19. Barcitinib is currently approved for treatment of rheumatoid arthritis and proposed mechanism of action in COVID 19 infections include reduction in cytokine mediated inflammation and potential antiviral activity.

Launched: August 3, 2020

- **PI**: Akram Khan, MD; **Coordinators**: PRISM Research Team
- **Inclusion:** > 18 yo, COVID + (within 72 hours) and presenting with disease progression, requires supplemental oxygen, elevated inflammatory markers
- **Exclusion:** receiving cytotoxic treatments or IVIg/convalescent plasma, received high dose corticosteroids or OAT3 inhibitors, current TB or active/serious infections
- **Status:** ACTIVE, **Enrolled: 19**
- **Contact:** Akram Khan, khana@ohsu.edu ; Olivia Krol, krolo@ohsu.edu ; page 11912

ACTIVE STUDIES

AF CDS tool
A stepped wedge clinical trial of an electronic clinical decision support tool to improve stroke prevention in patients with atrial fibrillation. Patient and providers will be recruited for qualitative interviews.

Launching: December 2021 at OHSU, then HMC and Adventist

- **PI:** Bory Kea, **Coordinator:** Joy Kim
- **Inclusion:** AF>17 years, OAC naïve
- **Contact:** Bory Kea, kea@ohsu.edu; Joy Kim, kimjoy@ohsu.edu

Beckman Heart Failure
The purpose of this study is to collect blood samples for the evaluation of the Access Natriuretic Peptide assay as an aid in the diagnosis of acute HF and assessment of severity of individuals suspected of having HF.

Launched: May 6, 2021

Enrolling between Tuesday – Friday from 9:00-4:00 PM.

- **PI**: Bory Kea, **Coordinator**: Joy Kim
- **Inclusion:** ≥21 years, presenting with a suspicion of acute HF
- **Exclusion**: Dyspnea not secondary to HF (lung disease, trauma, etc.), Stage 4 or 5 CKD, chronic dialysis, participation in a clinical study that may interfere with participation in this study.
- **Status**: Enrollin, **Enrolled: 4**
- **Contact**: Joy Kim, kimjoy@ohsu.edu

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 Metro West Ambulance.

Launched: **April 1, 2021**

- **PI**: Mo Daya, **Co-I**: Marty Schreiber **Coordinator**: Nancy Le, Sam Underwood
- **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: 33**
- **Contact**: Nancy Le, lena@ohsu.edu

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. This study will be conducted under EFIC (Exception from Informed Consent).

Launched: **March 2021** **Sites: OHSU and sites at Houston (2) and Seattle (1)**

- **PI**: Schreiber, **Coordinators**: Samantha Underwood and Keeley McConnell
- 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**: Sam Underwood, underwos@ohsu.edu

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 1000 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; **Study Coordinator**: Joy Kim
- **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:** Resuming in Feb. 2022; **Enrolled: 29**
- **Contact:** Joy Kim, kimjoy@ohsu.edu

ICECAP- Influence of Cooling Duration on Efficacy in Cardiac Arrest Patients (a SIREN Network study)

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**: Nancy Le
- Registered with ClinicalTrials.gov: NCT 04217551
- FDA IDE: William Meurer, G160072
- **Status**: Enrolling; **Enrolled: 34; All site total: 356**
- **Contact**: Nancy Le, lena@ohsu.edu

For more information: https://siren.network/clinical-trials/icecap

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, **Coordinators**: Keeley McConnell (TRG), Jenny Cook EM Coordinator
- Registered with ClinicalTrials.gov: NCT03754114
- **Status**: Enrolling; **Enrolled: OHSU: 16; All site total: 252**
- **Contact:** Keeley McConnell, mcconnke@ohsu.edu

For more information: https://www.ohsu.edu/school-of-medicine/emergency/boost-3-study

Digital Capillary Refill with HydraSense

Using a novel device (Hydrasense) to compare manual vs digital capillary refill: currently enrolling in patients 6mo-65yo.

This study requires NO work or input from RNs or MDs. The study team will work around staff with any patients they enroll to make sure and prioritize your time with them over the study.

Launched: **September 12, 2018**

- **PI**: Sheridan; **Coordinator**: Jordan Gillespie
- **Status**: Enrolling; **Enrolled**: **452**; Enrollment Goal: 600
- **Contact**: Jordan Gillespie, gillesjo@ohsu.edu

HydraSense for Sepsis

A novel device for distal perfusion: currently enrolling in patients 6mo-65yo with fever, sepsis, and ESI 2-3.

Launched: **June 24, 2019**

- **PI**: Sheridan; **Coordinator**: Jordan Gillespie
- **Status**: Enrolling; **Enrolled**: **79 sepsis enrollments**
- **Contact:** Jordan Gillespie; gillesjo@ohsu.edu

SAVE-O2 - Strategy to Avoid Excessive Oxygen for Critically Ill Trauma Patients

SAVE-O2 will be a multicenter cluster randomized, stepped wedge implementation trial of a multimodal educational intervention to target normoxia in adult trauma patients admitted to the intensive care unit

(ICU). The goal is to improve oxygenation to >90% of eligible patient-hours spent in the desired normoxia range, excluding time without supplemental oxygen or time on FiO2 100% and below the normoxia range.

Launched: October 15, 2020

- **PI**: Schreiber, **Coordinator**: Samantha Underwood
- **Inclusion**: Patients who meet criteria for entry into the OHSU trauma registry
- **Exclusion**: Age <18 years, Prisoners, Known pregnancy, Transferred patients not admitted through the emergency department
- **Status**: Active
- **Contact**: Samantha Underwood, underwos@ohsu.edu

CLOSED STUDIES

CLOTT2 - The Pathogenesis of Post traumatic Pulmonary Embolism

Investigation into the significance of incidentally discovered venous thromboembolism following trauma and the role of fibrinogen break down in the development of post-traumatic VTE.

Launched: May 2018

- **PI**: Kiraly, Laszlo; **Coordinator**: Dylan Payton
- **Inclusion**: >18 yo and ≥ 40 yo with ICU admission expected for ≥ 3 days and has at least on risk factor
- **Exclusion**: Outside of age range, direct admit to ward, and/or minor injuries
- **Status**: Closed; **Enrolled: OHSU: 85; All site: 137**

SWAT - Shock, Whole blood and assessment of TBI

Evaluate outcomes associated with early whole blood resuscitation practice as compared to component resuscitation in poly trauma patients with hemorrhagic shock and further characterize outcome benefits in those with TBI.

Launched: **November 2018**

- **PI**: Schreiber, Martin; **Coordinator**: Sean Van Walchren
- **Inclusion**: blunt or penetrating trauma who meet 2 or more of the following criteria (SBP < 90mmhg, penetrating mechanism, + FAST and/or Tachycardia); and receives at least 1 unit of blood and goes to the OR with in 60minutes of arrival.
- **Exclusion**: <15, CPR > 5 consecutive minutes without ROSC, penetrating TBI with brain matter exposed, ED death, know pregnancy and/or prisoner
- **Status**: Closed; **Enrolled: 112; All site total: 1050**

ACTIV-1 (IM) Immune Modulators for Treating COVID-19

Evaluate multiple immune modulating investigational agents for moderately - severely ill patients with COVID-19.

Launched: October 15, 2020
Study Duration: September 2021

- **PI**: Akram Khan, MD; **Coordinators**: PRISM Research Team
- **Inclusion**: > 18 yo., COVID + (within 14 days) and ongoing symptoms, expected to require hospitalization for > 72 hours, no co-enrollment
- **Exclusion**: high ALT/AST, neutropenia, lymphopenia, pregnant/breast-feeding, known allergy to agents, active infections other than COVID-19, severe cirrhosis, heart failure, or organ dysfunction

- **Status:** ACTIVE, **Enrolled**: **22**
- **Contact**: Akram Khan, khana@ohsu.edu ; Olivia Krol, krolo@ohsu.edu ; page 11912

Biology and Longitudinal Epidemiology of PETAL COVID-19 Observational Study (BLUE CORAL)

An observational study of patients with COVID-19. The study collects demographic, financial, and biological information through surveys, biospecimens, and post-discharge follow up calls.

Launched: August 2020
Study Duration: May 2021

- **PI:** Akram Khan, MD ; **Coordinators**: PRISM Research Team
- **Inclusion:** > 18 yo., COVID + with fever or respiratory symptoms
- **Exclusion:** failure to randomize within 72 hours of hospitalization, patients on comfort care, prisoners
- **Status:** Closed, **Enrolled: 126**
- **Contact**: Akram Khan, khana@ohsu.edu ; Olivia Krol, krolo@ohsu.edu ; page 11912

CLOVERS (Fluids vs. Vasopressors)

Evaluating if a liberal or restrictive fluid strategy is the more appropriate initial approach in patients with suspected infection and low blood pressure.

Launched: March 7, 2018
Study Duration: June 2021

- **PI**: Akram Khan, MD (khana@ohsu.edu); **Coordinators**: PRISM Research Team
- **Inclusion:** > 18 yo, suspected/confirmed infection (planned antibiotics), sepsis (systolic < 100 mmHg or MAP < 65 mmHg) or use of vasopressors after receiving 1 L of IV fluids
- **Exclusion:** Not able to be enrolled within of 4 hrs of meeting inclusion and within 24 hrs of presentation, received > 3 L of fluids, pregnant, hypotension at baseline, pulmonary edema, severe volume depletion NOT due to sepsis
- **Status:** Closed, **Enrolled**: **179**
- **Contact:** Akram Khan, khana@ohsu.edu ; Olivia Krol, krolo@ohsu.edu ; page 11912