July 2020 Updates on ED Clinical Trials

With a tumultuous last few months, 2020 is a year unlike any other. Your resiliency in the face of these crises and continued willingness to serve our community makes me proud to be part of the ED team. We're in this together, and we're not done yet. As the ED is at the forefront of care, we have the opportunity to change the trajectory of care. Research studies are up and running again with some modified protocols, and we have several active or soon-to-be active COVID-19 research studies—both diagnostic and interventional studies. Thank you to every member of our healthcare team.
–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

Clinical Evaluation of the BinaxNOW® COVID-19 Antigen (Ag) Card

The primary objective of this study is 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 a healthcare provider using nasal swabs. Staff will collect 2 nasal swabs from each subject. One nasal swab will be tested directly with BinaxNOW® COVID-19 Ag without elution in VTM. The other nasal swab will be placed in VTM. Swabs will be shipped to the Sponsor's central laboratory for reference testing.
Launch Date: **July 2020**

- **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**: In process of Regulatory Review
- **Contact:** Nancy Le, Clinical Research Coordinator: lena@ohsu.edu

C3PO- Clinical Trial of COVID-19 Convalescent Plasma of Outpatients – a SIREN Network Trial

The Clinical Trial of COVID-19 Convalescent Plasma in Outpatients (C3PO) is a multi-center randomized, single-blind, two-arm, placebo-controlled phase III trial with blinded outcome assessment to establish the safety and efficacy of a single dose of convalescent plasma (CP) for preventing the progression from mild to severe COVID-19 illness. This trial will be conducted in the OHSU Emergency Department.
Launch Date: **August 2020**

- **PI**: Bory Kea,; **Coordinator**: Jenny Cook
- **Status**: Pre-study Preparations – anticipated launch in August 2020
- Study has received approval from the COVID Registry Taskforce and may be conducted during Research Level 2 operations
- Registered with ClinicalTrials.gov: NCT04355767

ED COVID-19 Registry Subject Follow up Study

This prospective cohort study will follow subjects up to 30 days post their ED visit for any COVID-like Illness and be asked to consent to a weekly follow-up symptom survey for the 4 weeks following their ED visit. The purpose of this study is to learn more about the clinical course and outcomes of similar patients, and to help guide health systems and emergency departments during the current pandemic.
Sites: OHSU adult and peds EDs, and Tuality ED.

- **Co-PI's**: Craig Newgard, Esther Choo; **Coordinator**: Jenny Cook
- **Status**: Enrolling; **Launched**: April 17, 2020
- Study has received approval from the COVID Registry Taskforce and may be conducted during Research Level 3 operations
- # of subjects consented: **381**

Leronlimab for severe COVID-19 infection

Purpose: To examine the impact of leronlimab on progression during mild COVID–19 infection

- **PI**: Marcel Curlin, MD
- **Inclusion**: Age 18 and above, severe illness due to COVID-19 infection
- **Exclusion**: DNR status, requiring vasopressors for >24 hours, severe liver disease, end stage renal disease requiring chronic dialysis, other investigational treatment for COVID-19.
- Enrolled: **390**
- **Contact**: Amber Gordon (OCTRI) gordoamb@ohsu.edu

TJ003234 (Anti-GM-CSF Monoclonal Antibody)for moderate to severe COVID-19 infection

Purpose: To examine the impact of TJ 003234 on progression during severe COVID–19 infection

- **PI**: Marcel Curlin, MD
- **Inclusion**: Age 18 and above, moderate to severe illness due to COVID-19 infection
- **Exclusion**: Severe CAD, Severe preexisting pulmonary disease, severe renal impairment, severe hepatic disease, HIV/HBV/HCV/TB, immunomodulatory drugs, ECMO, pregnancy, recent live vaccination
- Enrolled: **24**
- **Contact**: Amber Gordon (OCTRI) gordoamb@ohsu.edu

ACTIVE STUDIES

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).

- **BOOST-3 PI**: David Zonies, **SIREN PI**: Daya, **Coordinators**: Keeley McConnell (TRG), Jenny Cook EM Coordinator
- Registered with ClinicalTrials.gov: NCT03754114
- **Status**: Enrolling; **Launched**: March 16, 2020
- Study has received approval to continue during Research Level 2 operations
- Enrolled: **OHSU: 1 All site total: 27**

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

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.

- **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**: Currently enrolling; **Launched**: May 2018
- **Contact**: Dylan Payton, paytond@ohsu.edu

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.

- **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**: Currently enrolling; **Launched**: November 2018
- **Contact**: Sean Van Walchren, vanwalch@ohsu.edu

Digital Capillary Refill with HydraSense

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

- **PI**: Sheridan; **Coordinator**: Nancy Le
- Enrolled: **351**; Enrollment Goal: 600
- **Status**: Currently enrolling; **Launched**: September 12, 2018

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.

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

- **PI**: Sheridan; **Coordinator**: Nancy Le
- Enrolled: **54**; Enrollment Goal: 100
- **Status**: Currently enrolling; **Launched**: June 24, 2019

Solace
Wearable technology for physiologic monitoring of adolescent suicidality: enrolls adolescents presenting with suicidality with goal of developing objective/physiologic markers that correlate with escalating suicidality.

- **PI**: Sheridan; **Coordinator**: Nancy Le
- Enrolled: **164**; Enrollment Goal: 200 across the pediatric ER and inpatient adolescent psychiatric unit at Unity
- **Status**: Currently enrolling with end date of December 2020; **Launched**: September 25, 2017

CLOVERS (Fluids vs. Vasopressors IRB 18184)
Goal is to find out if a liberal or restrictive fluid strategy is the more appropriate initial approach in patients with suspected infection and low blood pressure. Both arms are current standard of care with equipoise between the arms. Patients are enrolled in the ED.
Here is a link to a 5 min patient video that further explains the study.

- **PI**: Akram Khan (khana@ohsu.edu)
- **Status:** Currently enrolling; **Launched**: July 2018
- **Contact**: Smartweb à Last Name à PRISM (#11912) (8am to 9pm)

UPCOMING ED STUDIES

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. Additionally, OHSU is anticipating that 5-6 of its network partners will also participate in ICECAP.
Launch Date: **August 2020**. Sites: OHSU - Portland Adventist ED

- **ICECAP PI**: Daya, **Portland Adventist ICECAP PI**: Matthew Neth, **Coordinator**: Nancy Le
- Registered with ClinicalTrials.gov: NCT 04217551
- FDA IDE: William Meurer, G160072
- **Status**: Pre-study Preparation

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

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.
Launch Date: **Summer 2020**.

- **PI**: Schreiber, **Coordinator**: Samantha Underwood
- **Status**: Pre-study Preparation

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).
Launch Date: **September 2020**. 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
- **Status**: Pre-study Preparation