

January 2021 Updates on ED Clinical Trials

Well, 2021 did not start as we expected and I recognize these trials may be the farthest from your mind. I want you to know that what you do matters (in and out of the ED), and YOU matter. Be resilient. If you have some brain space for our trials, see below, as we continue to march forward to make sure SCIENCE matter.

–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

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- BD COVID-19
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COVID-19 STUDIES



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.

Rapid tests are available for research purposes only.

Any healthcare provider (RN, NP, PA, MD, or PharmD): PAGE #11502 to screen for C3PO!

- **PI:** Bory Kea; **Coordinator:** Jenny Cook

- **Status:** Launched 8/19/20; **Enrolled: 24; All sites: 394**
- **Order a Rapid COVID-19 test IF:**
 - ≥1 COVID-like sx for ≤7days
 - ≥18yo
 - ≥1 risk factor (age≥50y; HTN; diabetes; CAD; chronic lung disease; chronic kidney disease; immunosuppression; sickle cell disease, or obesity (body mass index [BMI]>30)
 - Likely to be d/c'd home
- Registered with ClinicalTrials.gov: [NCT04355767](https://clinicaltrials.gov/ct2/show/study/NCT04355767)
- **Contact:** Study coordinators: Jenny Cook cookjen@ohsu.edu, James Magas magas@ohsu.edu; PI: Bory Kea kea@ohsu.edu

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.

If ANY clinical staff suspects a patient of COVID-19 (there is no time limit on symptom duration), please page Trauma Research Group (TRG) at 11502.

- **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).
- **Enrolled: 136**
- **Status:** Enrolling
- **Contact:** Nancy Le, Clinical Research Coordinator: lena@ohsu.edu

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
- # of subjects consented: **381**

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

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:** Soon to open
- **Contact:** Ravi Chandra, chandrav@ohsu.edu

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

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

- **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:** 1
- **Contact:** Akram Khan, khana@ohsu.edu ; Olivia Krol, krolo@ohsu.edu ; page 11912

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

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

- **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:** 2
- **Contact:** Akram Khan, khana@ohsu.edu ; Olivia Krol, krolo@ohsu.edu ; page 11912

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

Evaluating the effects of prophylactic vs. therapeutic anticoagulation strategies on recovery time in adults hospitalized for COVID-19

- **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:** 15
- **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 Baricitinib in the treatment of patients with COVID 19. Baricitinib 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.

- **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, requires ventilation/ECMO on study entry
- **Status:** ACTIVE, **Enrolled:** 12
- **Contact:** Akram Khan, khana@ohsu.edu ; Olivia Krol, krolo@ohsu.edu ; page 11912

ACTIVE 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.

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; **Launched:** September 2020
- **Enrolled: 9; All site total: 109**

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).

- **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: 7 All site total: 111**

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 \geq 40 yo with ICU admission expected for \geq 3 days and has at least on risk factor
- **Exclusion:** Outside of age range, direct admit to ward, and/or minor injuries
- **Status:** 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:** 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:** 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:** 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: **181**; Enrollment Goal: 200 across the pediatric ER and inpatient adolescent psychiatric unit at Unity
- **Status:** Enrolling with end date of December 2020; **Launched:** September 25, 2017

CLOVERS (Fluids vs. Vasopressors IRB 18184)

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

Here is a [link to a 5 min patient video that further explains the study.](#)



Each mL contains
norepinephrine bitartrate
equal to 1 mg
norepinephrine base.
**DILUTE BEFORE USE.
PROTECT FROM LIGHT.**

4 mL Fill in 5 mL Vial
Single dose Flip-top Vial
Levophed®
norepinephrine bitartrate
injection, USP 4 mg/4mL (1 mg/mL)
FOR IV INFUSION ONLY
Warning: Contains Sulfites.
Hospira, Inc., Lake Forest, IL 60045 USA

NDC 0409-3375-04
LV45



- **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:** ACTIVE, **Enrolled:** 167
- **Contact:** Akram Khan, khana@ohsu.edu ; Olivia Krol, krolo@ohsu.edu ; page 11912

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: **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:** Enrolling
- **Contact:** Samantha 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.

Launch Date: **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:** Enrolling; **Enrolled:** 15
- **Contact:** Joy Kim, kimjoy@ohsu.edu

UPCOMING STUDIES

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: **January 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
- **Status:** Pre-study Preparation

BD COVID-19

A prospective, multi-center study with the purpose of collecting nasal swabs from people diagnosed or suspected of having COVID-19 to use in the future to help make new tests for detecting this virus and/or make current tests better.

- **PI:** Bory Kea, **Coordinator:** Nancy Le
- **Inclusion:** ≥ 18 years, presenting with COVID-19 symptoms: fever, dry cough, SOB, muscle pain, headache, sore throat, extreme tiredness, diarrhea, runny or stuffy nose, and new loss of taste or smell.
- **Exclusion:** Unable to collect all study swabs at time of collection
- **Status:** Pre-study preparations;
- **Site:** **Portland Adventist**
- **Contact:** Nancy Le, lena@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.

- **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:** Pre-study preparations
- **Contact:** Joy Kim, kimjoy@ohsu.edu

CLOSED STUDIES

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:** 391
- **Contact:** Amber Gordon (OCTRI) gordoamb@ohsu.edu