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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- ED COVID Registry
- Leronlimab
- TJ003234
- Covid PreVent Trial
- ACTIV-1 (IM)
- ACTIV-3 (TICO)
- ACTIV-4 (AC-INPT)
- COV-BARRIER

ACTIVE STUDIES

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- BOOST-3
- CLOTT2
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- HydraSense
- Solace
- CLOVERS
- SAVE-O2
- Fentalog (ToxIC)

UPCOMING STUDIES

- KCENTRA
- BD COVID-19
- Beckman HF

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.

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

- PI: Bory Kea; Coordinator: Jenny Cook
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.

- **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)
**ACTIVE STUDIES**

<table>
<thead>
<tr>
<th>Study Name</th>
<th>Description</th>
<th>Inclusion Criteria</th>
<th>Exclusion Criteria</th>
<th>Status</th>
<th>Contact</th>
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<tbody>
<tr>
<td>ICECAP</td>
<td>Influence of Cooling Duration on Efficacy in Cardiac Arrest Patients (a SIREN Network study)</td>
<td>&gt; 18 yo, COVID + (within 72 hours) and presenting with disease progression, requires supplemental oxygen, elevated inflammatory markers</td>
<td>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</td>
<td>ACTIVE, Enrolled: 12</td>
<td>Akram Khan, <a href="mailto:khana@ohsu.edu">khana@ohsu.edu</a>; Olivia Krol, <a href="mailto:krolo@ohsu.edu">krolo@ohsu.edu</a></td>
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<tr>
<td>BOOST 3</td>
<td>Brain Oxygen Optimization in Severe TBI Phase-3 Trial (a SIREN Network study)</td>
<td>&gt; 18 yo and ≥ 40 yo with ICU admission expected for ≥ 3 days and has at least on risk factor</td>
<td>Outside of age range, direct admit to ward, and/or minor injuries</td>
<td>Enrolling; Launched: September 2020</td>
<td>CLOTT2</td>
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### 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

- **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](#).
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

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)

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 vaspressors 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