April 2020 Updates on ED Clinical Trials

Thank you to every member of our healthcare team--your service keeps our hospitals running for our community. While many research studies have been put on pause, there are new studies on the horizon to support COVID-19 research. Look out for a future update on these studies as the ED is a critical site for both diagnostic and interventional studies. **–Bory Kea, 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

COVID Workforce Study

We're conducting a survey regarding the healthcare workforce during the COVID-19 pandemic. The survey should take about 3-8 minutes to complete. We hope that results of this survey will provide critical information on medical response efforts. Please send this out widely as ANYONE (MDs, RNs, LVNs, NP, PAs, EMTs, home health nurse, registration, valets, transportation, etc...) that encounters patients is eligible.

- PI: Kea and Hansen; Coordinator: Jenny Cook
- Inclusion criteria: >18yo, exposure to patients
- Exclusion: No patient exposure
- Responses: **2331**

Access the survey here: **www.ohsu.edu/covidworkforce**

Contact**:** cprem@ohsu.edu

ED COVID-19 Registry Subject Follow up Study

The ED COVID-19 Registry is a prospective cohort study that is following subjects up to 30 days post their ED visit for any COVID-like Illness. Subjects will 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. This study opened to enrollment on 4/17/2020. Sites include OHSU adult and peds EDs as well as Tuality ED.

- Co-PI's: Craig Newgard, Esther Choo; Coordinator: Jenny Cook
- Status: Enrolling
- Study has received approval from the COVID Registry Taskforce and may be conducted during Research Level 3 operations
- # of subjects consented: **66**

Messer Lab SARS-CoV-2/CoVID-19 Study

The Messer Lab in the Department of Molecular Microbiology and Immunology is conducting a study of early and late immune responses during and after infection with SARS-CoV-2/CoVID-19. This study is seeking subjects with confirmed diagnosis of SARS-CoV-2/CoVID-19 infection.

- PI: William Messer, MD-PhD
- Inclusion criteria: >=3 months old, laboratory confirmed infection with SARS-CoV-2/CoVID-19, English or Spanish speaking, non-pregnant, and felt to be safe for a nasopharyngeal swab or sputum sample collection, urine collection and up to a 60 mL blood draw for adults; 50 mL or 3 mL/kg for children.

Contact: Dr. Messer at 503-494-2185 (office), 919-593-3749 (cell), 1-5180 (pager), or messer@ohsu.edu.

For more information:
https://mcusercontent.com/0a4016dc40544f35724b8fdfd/files/ee05b20b-cfca-43e4-ae06-5fa265fb0f67/Messer_Lab.pdf

COVID-19 hydroxychloroquine pilot study

Purpose: To examine the impact of hydroxychloroquine on clinical, virologic and immunologic aspects of during early COVID–19 infection in patients at risk of severe disease

- PI: Marcel Curlin, MD
- Inclusion: Age 18 and above, early infection (within 5 days of symptom onset) risk of severe illness or respiratory impairment
- Exclusion: Prolonged QT syndrome, pregnancy, neuromuscular disorder, receipt of other investigational drug for COV ID–19
- Enrolled: **40**

Contact: Brett Rodgers rodgerbr@ohsu.edu, Shaadi Tabatabaei tabataba@ohsu.edu, Cory Woodyatt (ED)

COVID-19 enzalutamide study

Purpose: To examine the clinical, virologic and immunologic effects of enzalutamide on early COVID–19 infection in patients at risk of severe disease

- PI: Marcel Curlin, MD, Tom Beer, MD
- Inclusion: Men 18 and above, early infection (within 5 days of symptom onset) risk of severe illness or respiratory impairment
- Exclusion: Severe CAD, seizure disorder, pregnancy, active malignancy, use of gemfibrozil or trimethoprim, receipt of other investigational drug for COV ID–19
- Enrolled: **40**

Contact: Brett Rodgers rodgerbr@ohsu.edu, Shaadi Tabatabaei tabataba@ohsu.edu, Cory Woodyatt (ED)

Leronlimab for mild/moderate 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, mild-moderate illness due to COVID-19 infection
- Exclusion: Respiratory failure, ARDS, severe COPD, Severe liver disease, Renal failure, Uncontrolled systemic infection, Active malignancy, Other investigational agent for COVID-19
- Enrolled: **75**

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

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, immmunomodulatory drugs, ECMO, pregnancy, recent live vaccination
- Enrolled: **24**

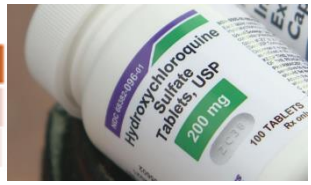
Contact: Amber Gordon (OCTRI) gordoamb@ohsu.edu

ORCHID (will hydroxychloroquine improve clinical outcomes among patients hospitalized with COVID-19? IRB 21360)

The study seeks to evaluate the efficacy and safety of hydroxychloroquine in COVID-19 patients. Enrolled subjects will receive study drug or placebo BID x 5 days. Subjects will receive 400 mg hydroxchloroquine/placebo BID on first day then 200 mg thereafter.

Subjects discharged before day 5 will continue drug at home.

	Day 1	Day 2	Day 3	Day 4	Day 5	Day 6
AM	400mg	200mg	200mg	200mg	200mg	
PM	400mg	200mg	200mg	200mg	200mg	



- PI: Akram Khan (khana@ohsu.edu)
- Contact: pager à 15351 or text/cell 503-449-4314 (24 hours).

6R88-COV-2040 (sarilumab vs placebo for COVID-19, IRB 21288)

The goal of this Adaptive phase 2/3, randomized double blind trial is to evaluate the efficacy and safety of sarilumab in patients hospitalized with COVID-19. Sarilumab is a monoclonial antibody approved in subcutaneous use for treatment of rheumatoid arthritis. Patients will be randomized in a 2:2:1 ratio to sarilumab 400 mg IV, 200 mg IV or placebo in a stratified manner. All enrolled patients will receive sarilumab/placebo at enrollment. Subjects who do not show clinical improvement may receive a second dose of sarilumab/placebo on day 2 then weekly for up to 6 doses.

- PI: Akram Khan (khana@ohsu.edu)
- Contact: pager à 15351 or text/cell 503-449-4314 (24 hours).

ACTIVE ED 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. OHSU is an “award hub”, and 4 of our OHSU network sites will also be participating in this trial (OSU, Duke, University of Utah, and University of Rochester Medical Center). A total of 45 sites will be enrolling patients throughout the duration of this trial. BOOST 3 allows for EFIC (Exception from Informed Consent) if an LAR is not present (within 6 hours).
Launch Date: **3/16/2020**.

- BOOST-3 PI: David Zonies, SIREN PI: Daya, Coordinator: Keeley McConnell (TRG), Jenny Cook EM Coordinator
- Registered with ClinicalTrials.gov: NCT03754114
- Status: Enrolling
- Study has received approval to continue during Research Level 3 operations
- Enrolled: **OHSU: 0 All site total: 27**

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.

- PI: Sheridan; Coordinator: Nancy Le

- Enrolled: **351**; Enrollment Goal: 600

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

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 (completed pilot of 76): **53**; Enrollment Goal: 200 across the pediatric ER and inpatient adolescent psychiatric unit at Unity

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: **Spring 2020.** Sites: OHSU and Portland Adventist.

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

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

KCENTRA

A multicenter, 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. 24-hour and 30-day mortality as well as organ failure and thromboembolic complications will be evaluated through day 30. This study will be conducted under EFIC (Exception from Informed Consent).
Launch Date: **May 2020**. Sites: OHSU and sites at Houston (2) and Seattle (1)

- PI: Schreiber, Coordinator: Samantha Underwood and Keeley McConnell
- Registered with ClinicalTrials.gov: NCT04019015
- FDA IND: Martin Schreiber, 18153

- Status: Pre-study Preparation

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). We define consensus-based normoxia target based on thresholds defined in our prior work—oxygen saturation (SpO2) 90-96% and when available, arterial oxygen pressure (PaO2) 60-100 mmHg. Intervention will start in the ED upon patient arrival and the intervention period will be the duration of the index ICU stay. 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: **Summer 2020**

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

ICU-ED SEPSIS STUDIES

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. Here is a link to a 5 min patient video that further explains the study.

Patients are enrolled in the ED. Some of these patients improve clinically and may be admitted to the floor. If admitted to your team, a coordinator will inform the resident and intern of patient's enrollment as well as write a note in the chart. If patient is in the restrictive arm and has received 3 L of fluid and needs vasopressors, patient will be transferred for further care to MICU. The MICU team is aware of the study and will accept transfers as needed. The goal in the restrictive arm is to avoid maintenance fluids or use of fluid boluses beyond 3 liters.

- PI: Akram Khan (khana@ohsu.edu)
- Contact our study team Smartweb à Last Name à PRISM (#11912) (8am to 9pm)

CLOSED ED STUDIES

Heart Failure Pro BNP

This study enrolled patients in the ED from June 2019 to February 2020, evaluating a new pro-BNP assay in patients with heart failure (for diagnosis and severity assessment).

- PI: Kea; Coordinator: Joy Kim
- Inclusion criteria: >22 yo and <50 yo and >74yo, male with SOB and/or edema; enrollment within 11hrs of presentation
- Exclusion: Trauma, on dialysis, prisoner, homelessness, and prior enrollment
- Enrolled: **56**