**Sharp HealthCare COVID Inpatient Treatment Clinical Trials**

**Updated July 31, 2020**

**Mild to Moderate**

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| **IRB #****Hospitals** | **Study** | **Primary Inclusion Criteria** | **Primary Exclusion Criteria** | **Investigators** | **Contact** | **Notes** |
| **2003902**SMHSGHSCV | **COVID-ARB** | -Mild to moderate respiratory symptoms, ---BP >100mmHg | -Severe allergy to any ARB, in ICU, home meds include ACE or ARB | SMH:SakoulasSMH:WillmsSMH: VasinaSGH: HaddadSCV: Shao | Cary Murphy, RN cary.murphy@sharp.com | Open to enrollment |

**Moderate**

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| **IRB #****Hospitals** | **Study** | **Primary Inclusion Criteria** | **Primary Exclusion Criteria** | **Investigators** | **Contact** | **Notes** |
| **2006903**SMHSCV | **MS200569-0026A Phase II, Randomized, Double‑blind, Placebo‑controlled Study to Evaluate the Safety and Efficacy of M5049 in Hospitalized Participants with COVID-19 Pneumonia** | - >18 and < 70-Not on vent or ECMO-SpO2 < 94% in room air AND able to maintain a PaO2/FiO2 ≥ 150 with a max FiO2 0.4 | -Clinically significant cardiovascular disease-Hx of uncontrolled illness prior to SARS-CoV-2 infection, within the past 3 months-Hx of the following:-HIV-Untreated hepatitis-Recurrent herpes-tuberculosis (TB) | SMH:El GhazalSCV: Shao | AdrianaValdez-HernandezAdriana.valdez-hernandez@sharp.com | Open to Enrollment |

**Moderate to Severe**

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| **IRB #****Hospital** | **Study** | **Primary Inclusion Criteria** | **Primary Exclusion Criteria** | **Investigators** | **Contact** | **Notes** |
| **2005701** | **MAYO Expanded Access to Convalescent Plasma for the Treatment of Patient with COVID-19** | -18+ years-Laboratory confirmed or clinically suspected infection w/ SARS-CoV-2-Severe or life threatening COVID-19, or judged by the treating provider to be at high risk of progression to severe or life-threatening disease-Severe COVID-19 is defined by one or more of the following:• dyspnea• respiratory frequency ≥ 30/min• blood oxygen saturation ≤ 93%• partial pressure of arterial oxygen to fraction of inspired oxygen ratio < 300• lung infiltrates > 50% within 24 to 48 hours-Life-threatening COVID-19 is defined as one or more of the following:• respiratory failure• septic shock• multiple organ dysfunction or failure |  | Any SHC Physician at SMH, SGH, SCOR and SCV | MacKenzie Habib mackenzie.habib@sharp.com | Open to enrollment based on avail. of plasma |
| **IRB #****Hospital** | **Study** | **Primary Inclusion Criteria** | **Primary Exclusion Criteria** | **Investigators** | **Contact** | **Notes** |
| **2005901**SGH**2005902**SCV | **GA42496 a phase II, randomized, double-blind,placebo-controlled, multicenter studyto evaluate the safety and efficacy ofMSTT1041A or UTTR1147A in patients withsevere covid-19 pneumonia** | -18+-Hospitalized and positive for COVID19 pneumonia by RT PCR and Chest Xray/Scan-SpO2 <93% or PaO2/FiO2 <300mmHg | -Progression to death is imminent within 24hrs;-High-dose corticosteroids within 72hrs- pregnant or breastfeeding-Not participating in another drug trial including CCP | SGH: OvercashSCV: Waters | Shandel Odomsodom@estudysite.comRosalynn Landazurirlandazuri@estudysite.com | Open to enrollmnt |
| **2005903**SGH**2005904**SCV | **CMAS825F12201: A Phase 2, randomized, placebo-controlled, participant and investigator blinded, multi-center study to assess efficacy and safety of MAS825 for the treatment of SARS-CoV-2 infected patients with COVID-19 pneumonia and impaired respiratory function** | -18-80-SARS-CoV-2 diagnosis by PCR within 7 days prior to randomization-Hospitalized with COVID-19 induced pneumonia evidenced by chest Xray/CTscan/MRI within 5 days prior to randomization-SpO2 <=93% or PaO2/FiO2<300mmHg | -APACHEII >=10 (acute physiology score+age points+chronic health points. Increasing score associated with increasing risk of hospital death)-weight 45-120kg-No other bacterial, fungal, viral or other infection-Progression to death is not imminent within next 24 hours-Not intubated at randomization | SGH: OvercashSCV: Waters | Erica Sanchezesanchez@estudysite.comDalia Toverdtover@estudysite.com | Open to enrollmnt |
| **2006902**SMHSGHSCV | **GAM10-10: Efficacy and Safety of Octagam 10% Therapy in COVID-19 Patients with Severe Disease Progression** | 18+-Resting Sp02 of <93% requiring oxygen supplementation

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 | -History of allergic reaction to IVIG-Recent TEE-Underlying medical condition that can lead to hypercoagulable states and hyperviscosity- Hx of IgA deficiency- Vented- rec’d CCP- rec’d IVIG products- Anti-interleukin agentsInterferons | SMH:Sakoulas, Willms, Salem,SGH:Haddad | Cary Murphy, RN cary.murphy@sharp.comMatthew Geriak, PharmDMatthew.geriak@sharp.com | Open to Enrollmnt |
| **IRB #****Hospital** | **Study** | **Primary Inclusion Criteria** | **Primary Exclusion Criteria** | **Investigators** | **Contact** | **Notes** |
| **2007903**SMHSGHSCV | **A Randomized Double-Blind, Placebo-Controlled, Parallel-Group Phase 3 Study of Baricitinib in Patients with COVID-19 Infection: 14V-MC-KHAA** | -18+-PCR+ < 72 hours-Sp02 < 94 or Pa02/Fi02 ratio <300mmHg->UNL (CRP, D-Dimer, LDH, Ferritin) | -receiving cytotoxic or biologic tx- washout req’d for:B-cell, TNF inhibitors, JAK inhibitors-rec’d CCP or IVIG- corticosteroids > 20 mg/day for 14 days-TB-bacterial, fungal, viral or other non-COVID infection- Live vaccine w/in 4 wk-ECMO-current malignancy-VTE, PE w/in 12 wks-neutropenia-lymphopenia-ALT or AST > 5 times ULN-eGFR <30mL/min/1,73m2 | SMH: Lawrie, El GhazalSGH: HaddadSCV: Shao | Divina Fanning, RNDivina.fanning@Sharp.com | Open to enrollmnt |

**Severe**

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| **IRB #****Hospital** | **Study** | **Primary Inclusion Criteria** | **Primary Exclusion Criteria** | **Investigators** | **Contact** | **Notes** |
| **2007904**SMHSGHSCV | **Phase 2/3 clinical study with mavrilimumab (KPL-301), an anti-GM-CSF inhibitor, for patients hospitalized with severe COVID-19 pneumonia and systemic hyper-inflammation** | -18+-COVID+ w/in 14days-Bilateral pneumonia- Fever > 100- one of the following:Ferritin > 500ng/mLCRP>5 mg/dLD-Dimer >1,000LDH > 250 U/LIntubated or non-intubated | -Onset of sx> 14 days-hosp > 7 days- Need ECMO- Hx of PAP- Hx of immunodef.-Hx solid organ or bone marrow transplant-current systemic immune-modulating RX-current cytotoxic chemotherapy- Severe asthma, COPD- LVEF < 35%- TB- bacterial or fungal infection- SARs, MERS-Chronic liver disease- QTcF ECG > 450ms-chronic or recent (7days) corticosteroid use >10mg/day | SMH:Lawrie,Willms | Divina Fanning, RNDivina.fanning@Sharp.com | Open mid-August |
| **2006901**SGHSCV | **WA42511 REMDACTA, A phase III, randomized, double-blind, multicenterstudy to evaluate the efficacy and safety ofRemdesivir plus Tocilizumab compared withRemdesivir plus Placebo in hospitalized patientswith severe covid-19 pneumonia** | -18+-Hospitalized with Covid-19 pneumonia confirmed per positive PCR and evidenced by CXR or CT scan-Requiring >6 L/min supplemental O2 to maintain SpO2 >93%-Can be intubated (not required) | -Allergies to TCZ or other monoclonal antibodies, or hypersensitivity to remdesivir- Active TB infection; bacterial, fungal, viral, or other infection (besides Covid-19)- Tx with TCZ within last 3 months-Concurrent tx with other agents or possible direct-acting antiviral activity against SARS-CoV-2 within 24hrs prior to dosing- GFR <30 mL/min-ALT/AST >5 ULN- ANC <1,000- Platelets <50,000- body weight <40kg; pregnant or breastfeeding | SGH and SCV: Overcash |  | Open to Enrollmnt |

**Vented**

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| **IRB #****Hospital** | **Study** | **Primary Inclusion****Criteria** | **Primary Exclusion****Criteria** | **Investigators** | **Contact** | **Notes** |
| **2007902**SCVSGHSMH | **18424-369A Phase 3 randomized, double-blind, placebo-controlled, multi-center study to assess the efficacy and safety of ruxolitinib in patients with COVID-19-induced ARDS who require invasive mechanical ventilation (RUXCOVID-DEVENT)** | -18+-COVID+ < 3 weeks-Vented- Pa02/Fi02 of < 300mmhg w/in 6 hrs of randomization- bilateral or diffuse pulmonary infiltrates on chest x-ray or CT scan | - sensitivity to drugs in same class- severely impaired renal function- uncontrolled bacterial, fungal or other infection besides COVID-19-TB-Unlikely to survive 24h-ECMO | SCV: ShaoSGH: HaddadSMH: El Ghazal | AdrianaValdez-HernandezAdriana.valdez-hernandez@sharp.com | Open to enrollmnt |
| **2006901**SCVSGH | **WA42511 REMDACTA, A phase III, randomized, double-blind, multicenterstudy to evaluate the efficacy and safety ofRemdesivir plus Tocilizumab compared withRemdesivir plus Placebo in hospitalized patientswith severe covid-19 pneumonia** | -18+-Hospitalized with Covid-19 pneumonia confirmed per positive PCR and evidenced by CXR or CT scan-Requiring >6 L/min supplemental O2 to maintain SpO2 >93%-Can be intubated (not required) | -Allergies to TCZ or other monoclonal antibodies, or hypersensitivity to remdesivir- Active TB infection; bacterial, fungal, viral, or other infection (besides Covid-19)- Tx with TCZ within last 3 months-Concurrent tx with other agents or possible direct-acting antiviral activity against SARS-CoV-2 within 24hrs prior to dosing- GFR <30 mL/min-ALT/AST >5 ULN- ANC <1,000- Platelets <50,000- body weight <40kg; pregnant or breastfeeding | SGH and SCV: Overcash |  | Open to Enrollmnt |
| **2007901**SMH | **Covid-19 trial of the use of Attune Medical esophageal cooling/warming device to treat ventilated Covid-19 patients with core warming** | -18+-Vented-Max baseline temp w/in 12hr <38.3- Has LAR | - No LAR- Contraindication to Core Warming- Pregnant- 40 kg body mass- DNR status- acute stroke, post-cardiac arrest or MS | SMH: Willms, Salem | Kyra CloutierKyra.cloutier@sharp.com | Open to Enrollment |

**Closed to Enrollment**

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| **IRB #****Hospital** | **Study** | **Principal Investigator** | **Date Closed** | **Number enrolled at SHC** |
| **2004901**SCVSGHSMH | **WA42380 A Randomized, Double-Blind, Placebo-Controlled, Multicenter Study To Evaluate The Safety And Efficacy Of Tocilizumab In Patients With Severe COVID-19 Pneumonia** | Michael Waters, MD | **5/26/20** | **27** |
| **2004902**SMHSGH | **COVID-IVIG: Randomized Open Label Study of Standard of Care Plus Intravenous Immunoglobulin (IVIG) Compared to Standard of Care Alone in the Treatment of COVID-19 Infection** | George Sakoulas, MD | **6/18/20** | **34** |
| **2005905**SCV | **Covid-019, protocol ml42528. A randomized, double-blind, placebo-controlled, multicenter study to evaluate the efficacy and safety of tocilizumab in hospitalized patients with covid-19 pneumonia EMPACTA** | Michael Waters, MD | **7/20/20** | **10** |