**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**  SMH  SGH  SCV | **COVID-ARB** | -Mild to moderate respiratory symptoms, ---BP >100mmHg | -Severe allergy to any ARB, in ICU, home meds include ACE or ARB | SMH:Sakoulas  SMH:Willms  SMH: Vasina  SGH: Haddad  SCV: 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**  SMH  SCV | **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 Ghazal  SCV: Shao | Adriana  Valdez-Hernandez  Adriana.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 study to evaluate the safety and efficacy of MSTT1041A or UTTR1147A in patients with severe 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: Overcash  SCV: Waters | Shandel Odom  [sodom@estudysite.com](mailto:sodom@estudysite.com)  Rosalynn Landazuri  rlandazuri@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: Overcash  SCV: Waters | Erica Sanchez  [esanchez@estudysite.com](mailto:esanchez@estudysite.com)  Dalia Tover  dtover@estudysite.com | Open to enrollmnt |
| **2006902**  SMH  SGH  SCV | **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   |  | | --- | |  | | -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 agents  Interferons | SMH:Sakoulas, Willms, Salem,  SGH:Haddad | Cary Murphy, RN cary.murphy@  sharp.com  Matthew Geriak, PharmD  Matthew.geriak@sharp.com | Open to Enrollmnt |
| **IRB #**  **Hospital** | **Study** | **Primary Inclusion Criteria** | **Primary Exclusion Criteria** | **Investigators** | **Contact** | **Notes** |
| **2007903**  SMH  SGH  SCV | **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 Ghazal  SGH: Haddad  SCV: Shao | Divina Fanning, RN  Divina.fanning@  Sharp.com | Open to enrollmnt |

**Severe**

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| **2007904**  SMH  SGH  SCV | **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/mL  CRP>5 mg/dL  D-Dimer >1,000  LDH > 250 U/L  Intubated 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, RN  Divina.fanning@  Sharp.com | Open mid-August |
| **2006901**  SGH  SCV | **WA42511 REMDACTA, A phase III, randomized, double-blind, multicenter study to evaluate the efficacy and safety of Remdesivir plus Tocilizumab compared with Remdesivir plus Placebo in hospitalized patients with 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**  SCV  SGH  SMH | **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: Shao  SGH: Haddad  SMH: El Ghazal | Adriana  Valdez-Hernandez  Adriana.valdez-  hernandez@  sharp.com | Open to enrollmnt |
| **2006901**  SCV  SGH | **WA42511 REMDACTA, A phase III, randomized, double-blind, multicenter study to evaluate the efficacy and safety of Remdesivir plus Tocilizumab compared with Remdesivir plus Placebo in hospitalized patients with 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 Cloutier  Kyra.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**  SCV  SGH  SMH | **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**  SMH  SGH | **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** |