**Sharp HealthCare COVID-19**

**Inpatient Treatment Clinical Trials**

**Updated September 25, 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, ---SBP >110mmHg; Screen within 3 days of COVID-19 test | -Severe allergy to any ARB or ACE inh, in ICU, home meds include ACE or ARB;  CrCl < 30ml/min | SMH:Sakoulas  SGH: Haddad  SCV: Shao | Matthew Geriak, PharmD; [matthew.geriak@sharp.com](mailto:matthew.geriak@sharp.com); 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** |
| **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  Enrollment |
| **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 Enrollment |
| **2006902**  SMH  SGH  SCV | **GAM10-10: Efficacy and Safety of Octagon 10% Therapy in COVID-19 Patients with Severe Disease Progression** | 18+  -Resting Sp02 of <93% requiring oxygen supplementation  PaO2/FiO2 ratio  < 300 mmHg   |  | | --- | |  | | -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](mailto:Matthew.geriak@sharp.com) | Open to Enrollment |
| **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 | Cary Murphy, RN  Cary.murphy@  sharp.com | Open to Enrollment |

**Severe**

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| **IRB #**  **Hospital** | **Study** | **Primary Inclusion Criteria** | **Primary Exclusion Criteria** | **Investigators** | **Contact** | **Notes** |
| **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 | Cary Murphy, RN  Cary.murphy@  sharp.com | Open to Enrollment |
| **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 Enrollment |
| **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**  ***COHORT 1*** | -18+  - + COVID test w/in 14 days of randomization  -Bilateral pneumonia on x-ray or CT  -fever >100.4°F or >38.2°C  -ferritin>500mg/mL or CRP > 5mg/dL or D-dimer>1,000ng/mL or LDH>250U/L  - receiving non-invasive ventilation/  oxygenation to maintain SpO2 > 92% and non-intubated | -hosp > 7 days prior to rand.  -need for invasive mechanical ventilation  -need for ECMO  -live vaccine w/in 4 weeks  -chronic or recent corticosteroid use > 10mg/day  -serious or concomitant illness that in the opinion of the investigator precludes subject enrolling in trial – e.g., hx of PAP, immunodeficiency, solid organ or bone marrow transplant, current use of mavrilimumab, active cancer within 10 years (except basal and squamous of skin)or in situ carcinoma of cervix now cured, severe, uncontrolled pulmonary disease other than COVID-19, left ventricular systolic dysfunction, active TB, uncontrolled bacterial or fungal infection, SARS or MERS (per investigator opinion), chronic liver disease.  - recent tx with cell-depleting biological therapies within 12 mos., anakinra, anti-IL-6 receptor within 8 wks, cyclosporine A, azathioprine, cyclophosphamide, MMF, CCP or other immunosuppressant w/in 4 weeks prior to randomization. | SMH: Lawrie, Willms  SGH:  SCV: | Cary Murphy, RN  Cary.murphy@  Sharp.com | Open to Enrollment |

**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 Enrollment |
| **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 Enrollment |
| **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 |
| **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**  ***COHORT 2*** | -18+  -Vented w/in 48 hours  -Bilateral pneumonia on x-ray or CT  -fever >100.4  -ferritin>500mg/mL or CRP > 5mg/dL or D-dimer>1,000ng/mL or LDH>250U/L | hosp > 7 days prior to rand.  -need for invasive mechanical ventilation  -need for ECMO  -live vaccine w/in 4 weeks  -chronic or recent corticosteroid use > 10mg/day  -serious or concomitant illness that in the opinion of the investigator precludes subject enrolling in trial – e.g., hx of PAP, immunodeficiency, solid organ or bone marrow transplant, current use of mavrilimumab, active cancer within 10 years (except basal and squamous of skin)or in situ carcinoma of cervix now cured, severe, uncontrolled pulmonary disease other than COVID-19, left ventricular systolic dysfunction, active TB, uncontrolled bacterial or fungal infection, SARS or MERS (per investigator opinion), chronic liver disease.  - recent tx with cell-depleting biological therapies within 12 mos., anakinra, anti-IL-6 receptor within 8 wks, cyclosporine A, azathioprine, cyclophosphamide, MMF, CCP or other immunosuppressant w/in 4 weeks prior to randomization | SMH: Lawrie, Willms  SGH:  SCV: | Cary Murphy, RN  Cary.murphy@  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** |
| **2005701** | **MAYO Expanded Access to Convalescent Plasma for the Treatment of Patient with COVID-19** | All SHC Physicians | **8/31/20** | **211** |