**Clinical trial guidance for Mount Sinai Nursing**

**Study sponsor**: Roche

**Study acronym:** CROSSWALK-acute

**Study title**: A phase Ib randomized, placebo-controlled study evaluating the safety, pharmacokinetics, pharmacodynamics, and efficacy of crovalimab for the management of acute uncomplicated vaso-occlusive episodes in patients with sickle cell disease (SCD)

**Study arms**: Crovalimab vs placebo (randomized 2:1 single dose IV)

**Approvals**: IRB, ED medical/nursing leadership, Pharmacy

*For study-related questions/issues, please contact:*

* *Clinical Trials Research Coordinator*: 646-960-1911 (weekday daytime)
* *Clinical Trials Manager*: 201-423-3585 (weekday daytime)
* *Site Principal Investigator*: Jonathan Schimmel, MD, via Epic Secure Chat or 646-818-9502 (**24/7**)

**Study summary**

* Placebo-controlled, double-blind, randomized, study on efficacy/safety of crovalimab to treat vaso-occlusive episode (VOE) pain crisis in Sickle Cell Disease (SCD).
* Crovalimab is an investigational humanized monoclonal antibody that inhibits a part of the immune system called complement (C5 inhibitor).
* *Trial rationale*: Complement activation has been implicated in SCD to have a role in vaso-occlusion, hemolysis, and inflammation, so inhibiting it may improve SCD.
* Subjects get a monetary stipend for participation.

**Eligibility**

* Research Coordinators determine eligibility and obtain consent.
* Adult (18-85) with SCD and uncomplicated pain crisis defined as acute pain <48 hours with no cause other than VOE, requiring IV/IM opioids, and admission or RETU.
  + Excluded if VOE pain >48 hours before ED arrival, acute chest syndrome, suspected severe infection, or >10 VOEs in past 12 months.

**Research labs**

* This trial collects research-only lab tests not ordered in Epic. The research coordinator will draw the specimens or hand you specific tubes to draw.
  + Research Coordinators will attempt blood draws, but may need assistance. They will tell you what time windows to anticipate for phlebotomy.
* Time points for lab draws
  + Pre-infusion
  + Post-infusion: 0-30 min
  + Post-infusion: 12 hours (±6 hours)
  + Post-infusion: Days 2, 6, 10, 14, 28, 84 and/or the day of discharge

**Drug**

* A single IV dose is given: 1,000 mg (weight ≥40 to <100 kg) or 1,500 mg (weight ≥100 kg).
* Epic order: “GCO#21-1595 (BO42452-ED) Crovalimab/placebo in sodium chloride 0.9% 100 mL infusion”
* Research Coordinators bring the drug from pharmacy to RN (not via tube station).
  + Drug/placebo look identical.
* Administration instructions
  + Use 0.2 micron in-line filter.
  + Scan the patient wristband and drug barcode before administration.
  + Infuse 1,000 mg over 60 min at a rate of 100 mL/hour, or
  + Infuse 1,500 mg over 90 min at a rate of 66 mL/hour.
  + Flush line with saline at same rate as the infusion to ensure delivery of full dose.

**Risks**

* Increased susceptibility to infections (especially encapsulated bacteria).
* Hypersensitivity and infusion-related reactions, can range from a mild rash to anaphylaxis.
* Notify the provider/study team immediately for new signs, symptoms, or vital sign changes.

**Monitoring**

* Patients do not require telemetry.
* Record times precisely (vitals, drug administration, blood draw collection).
* Record vitals accurately (eg respiratory rate, well-fitting BP cuff).