Clinical trial guidance for Mount Sinai Nursing

Study sponsor: Comprehensive Research Associates
Study acronym: PLATINUM
Study title: A multicenter, randomized, double-blind, placebo controlled, parallel group phase 4 study of the efficacy and safety of patiromer for oral suspension in combination with standard of care treatment in emergency department patients with hyperkalemia (PLATINUM)
Study arms: Patiromer (oral suspension) vs placebo (randomized 1:1)
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 an oral drug already approved for hyperkalemia.
- No oral drug is approved for hyperkalemia emergency treatment (eg kayexalate, Lokelma, patiromer).
- This trial examines speed of potassium lowering, *in addition to* standard therapy (insulin, albuterol, etc).
- Subjects get a monetary stipend for participation.

Eligibility

- Research Coordinators determine eligibility and obtain consent.
- Adults with potassium ≥ 5.8.
    - Excluded if expected to get dialysis in 6 hours, cannot swallow liquid, or in the past week took an oral potassium binder (kayexalate, patiromer, Lokelma).

Assessments

- Labs are tested in the Mount Sinai lab. This trial does not use special research tubes for blood.
- *Please document accurate blood draw times in an Epic note.*
    - Research Coordinators will attempt blood draws, but may need assistance. They will tell you what time windows to anticipate for phlebotomy, based on when drug is given.
- Assessment 1 (baseline)
    - Height/weight (Research Coordinator assists)
    - Vitals
    - ECG (if not already done)
    - Measure potassium, magnesium
- Assessment 2 (hour 2)
    - Measure potassium
- Assessment 3 (hour 4)
    - ECG
    - Measure potassium
- Assessment 4 (hour 6)
    - Measure potassium, magnesium
- Assessment 5 (hour 8)
    - Measure potassium
- Assessment 6 (hour 10, or when the patient physically leaves the ED for discharge or admit)
    - Measure potassium
- Follow-up is done by the research team.

Drug info

- Epic order: "GCO#21-0585 patiromer/placebo packets for oral suspension."
- Research Coordinators bring the drug from pharmacy to RN (not via tube station).
- Administration instructions
    - Prepare the drug by measuring 80mL of water (non-sterile). Pour half the water in a cup, then add 3 drug packets and stir, then add the remaining water and stir.
    - The powder will not dissolve, the mix will be cloudy. Can add more water for desired consistency.
    - Scan the patient wristband and drug barcode then start infusion
        - Note the start time that Epic lists
    - After the patient drinks it, if powder remains in the cup, add more water and stir, and the patient should drink immediately. Repeat as needed to ensure the full dose is given.
- ***Document drug administration time a note***. This defines Hour 0 for the trial.
- Research Coordinator will take the remaining 4th packet, for Dose #2 in 24 hours.

Risks

- Risks are low with uncommon hypokalemia, hypomagnesemia, diarrhea, constipation, or bloating.
- Notify the provider team immediately for new signs, symptoms, or vital sign changes.

Monitoring

- No specific monitoring is required for this drug. Treating team may order telemetry for hyperkalemia.
- Record times precisely (vitals, drug administration, blood draws).
- Record vitals accurately (eg respiratory rate, well-fitting BP cuff).