

Title: Outpatient Recovery from acute Kidney Injury requiring Dialysis (ORKID)

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Outpatient Recovery from acute Kidney Injury requiring Dialysis (ORKID) Protocol

Summary: There are currently no therapies to improve the chances of recovering enough kidney function to come off of dialysis after severe acute kidney injury. It is not known if current routine outpatient dialysis treatments are optimized to maximize the chances of recovery. This is a single-center (multi-clinic), single-arm, non-randomized pilot study to investigate the feasibility, tolerability, and safety of a bundled intervention (cooled dialysate, high sodium dialysate, high dose diuretics, high ultrafiltration hold threshold, active dialysis weaning) designed to foster recovery from acute kidney injury requiring dialysis.

Inclusion Criteria:

- AKI-D, attributed at least in part to acute tubular necrosis by clinical nephrology team
- Age \geq 18 years
- Pre-hospitalization eGFR \geq 15 mL/min/1.73m²
- Being discharged to a participating outpatient dialysis unit (within 30 miles of UCSF)

Exclusion Criteria:

- Known loop diuretic allergy/intolerance
- Dialysis duration $>$ 3 months
- Pregnant, Prisoner, or Unable to consent
- Clinical team declines to allow approach for study

Intervention: During the 90-day study period, participants will be prescribed outpatient hemodialysis with cooled dialysate (35-36°C), high sodium dialysate (145 mmol/L), a high ultrafiltration hold threshold (systolic blood pressure $>$ 110 mmHg; ultrafiltration hold threshold will not be applied in participants with baseline systolic blood pressure $<$ 120 mmHg), and high dose diuretics (160 mg oral furosemide twice daily) to be taken every day at home will also be prescribed. Dialysis will be weaned according to an active weaning protocol.

Outcomes:

- Primary: Feasibility – the proportion of patients who received the dialysate temperature, dialysate sodium concentration, diuretic dose, and ultrafiltration hold threshold that was ordered at least once in the first two weeks of treatment.
- Secondary: Tolerability - the proportion of enrolled patients completing the 90-day study still continuing each intervention. Safety - Incidence of adverse events including electrolyte abnormalities, emergent dialysis treatments, and hospitalizations. Time to renal recovery - Days after study enrollment before renal recovery, defined as being alive and off dialysis for 14 consecutive days. Intradialytic hypotension – proportion of dialysis sessions with nadir systolic blood pressure $<$ 90 mmHg. Recruitment rate - number of participants enrolled per month. Screening-to-recruitment ratio - ratio of the number of participants who meet inclusion criteria to the number of participants enrolled. Modified dialysis symptom index score. Kidney disease quality of life-36 score.

Statistical Analysis Plan: We will perform descriptive statistics on the outcome variables.