Evaluation of the Effectiveness of Oral Hydration Compared to Intravenous Hydration in Preventing Contrast-Associated Acute Kidney Injury in the Emergency Department : A Randomized Controlled Non-Inferiority Trial

Document Date: November 7, 2025 **Study Setting:** Gaziosmanpasa Training and Research Hospital, Emergency Department

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1. STUDY SUMMARY AND RATIONALE

Contrast-enhanced imaging in the emergency department (ED) carries a risk of Contrast-Associated Acute Kidney Injury (CA-AKI). While intravenous (IV) hydration with isotonic sodium chloride is the recommended prophylaxis, it is resource-intensive and often difficult to implement within the time constraints of the ED. Oral hydration offers a non-invasive, low-cost, and easily applicable alternative that has shown non-inferiority in other clinical settings. This study aims to evaluate whether oral hydration is non-inferior to IV hydration in preventing CA-AKI among adult ED patients.

2. OBJECTIVES AND HYPOTHESES

- **Primary Objective:** To investigate if oral hydration is as effective as IV hydration in preventing CA-AKI.
- **Secondary Objectives:** To identify risk groups for CA-AKI and compare both methods regarding dialysis requirement, mortality, and cost-effectiveness.
- **Hypothesis (Non-inferiority):**
    - **H0:** Oral hydration is clinically significantly worse than IV hydration.
    - **H1:** Oral hydration is non-inferior or equivalent to IV hydration.

3. STUDY DESIGN AND METHODOLOGY

- **Design:** Randomized, controlled, open-label, non-inferiority study.
- **Allocation:** 1:1 ratio using stratified block randomization based on age and gender.
- **Population:** 198 adult patients (99 per group) with eGFR between 15–59 mL/min/1.73 m^2.

Interventions:

1. **IV Hydration Group (Active Comparator):** 0.9% NaCl solution. 3 mL/kg for 1 hour pre-procedure, followed by 2 mL/kg/hour for 4 hours post-procedure.
2. **Oral Hydration Group (Experimental):** Drinking water. 500 mL 1 hour pre-procedure, followed by 125 mL/hour for 4 hours post-procedure under nursing supervision.

- *Note: For patients with EF <40%, hydration doses are halved in both groups*.

4. ELIGIBILITY CRITERIA

- **Inclusion Criteria:** Age 18 and older ; eGFR 15–59 mL/min/1.73 m²; undergoing contrast-enhanced CT in the ED; signed informed consent.
- **Exclusion Criteria:** Pregnancy; ESRD or eGFR <15; dialysis; decompensated heart failure; contrast allergy; contrast exposure within last 72 hours; contraindication to oral intake.

5. OUTCOME MEASURES

- **Primary Outcome:** Incidence of CA-AKI (defined by ESUR 10.0 criteria: serum creatinine increase (0.3 mg/dL or 50% from baseline) measured 48–72 hours post-procedure.
- **Secondary Outcomes:** Requirement for dialysis within 1 month, all-cause mortality, and creatinine levels at 30–45 days.

6. STATISTICAL ANALYSIS PLAN (SAP)

Sample size was calculated based on an expected CA-AKI rate of 6.2% for IV hydration and a non-inferiority margin of 9%, with (α) = 0.05 and power (1-β) = 0.80. Categorical data will be analyzed using Pearson Chi-Square or Fisher's Exact test. Continuous data will be compared using Student’s t-test or Mann-Whitney U test depending on normality (Kolmogorov-Smirnov test). $P < 0.05$ is considered statistically significant.

7. ETHICAL CONSIDERATIONS

The study will be conducted in accordance with the Declaration of Helsinki and Good Clinical Practice (GCP) guidelines. Written informed consent will be obtained from all participants. Patient confidentiality will be strictly maintained.