



Data Creation Plan for Secondary Analyses

Name and Number of Study	Timing of Initiation of Renal Replacement Therapy in Patients with Cardiogenic Shock: A Subgroup Analysis of the STARRT-AKI Study
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DCP Update History	September 18, 2026 (Version 1.0)
Short Description of Research Question	Urgent decongestion is considered essential for patients with cardiogenic shock and volume overload, given the potential for improved stroke volume and cardiac output through reduction in ventricular end-diastolic volume, reduced myocardial ischemia through reduction in ventricular end-diastolic pressure, and improved renal function from reduction in renovascular congestion. Renal replacement therapy (RRT) is often used in patients with cardiogenic shock and acute kidney injury, primarily to aid in decongestion, however optimal timing for initiation of RRT in this population remains unclear. In this analysis, we asked the following question: Among participants from the STARRT-AKI cohort with cardiogenic shock, defined as the receipt of levosimenden, dobutamine, or milrinone at the time of randomization, what is the association between use of an accelerated RRT initiation strategy and clinical outcomes?
List of Datasets Used	STARRT-AKI cohort dataset, including data from the following CRF forms: • Form 5: Demographics & Details of Hospitalization • Form 6: Risk Factors • Form 7: Pre-randomization SOFA • Form 8: Pre-randomization Severity of Illness • Form 9: Pre-randomization Data • Form 10: Daily Data • Form 11: Physiological Parameters at RRT Initiation • Form 12: Adverse Event Data • Form 14: ICU and Hospital Discharge Data (Index Hospitalization Discharge) • Form 15: Resource Utilization Through Day 28 • Form 16: Day 90 Outcome Data • Form 17: Death- General Information • Form 20: Day 365 Outcome Data

Time of Data Extraction	Initial data extraction: June to July 2026 Additional data extraction: September 2026
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Defining the Cohort	
Cohort	Participants randomized in the STARRT-AKI trial with cardiogenic shock: defined as the receipt of inodilator therapy in the form of levosimendan, dobutamine, or milrinone at the time of randomization.
Exclusion Criteria	N/A
Size of Cohort	312

Time Frame Definitions	
Accrual Start/End Dates	STARRT-AKI trial enrolment period
Max Follow-up Date	365 days following randomization

Variable Definitions	
Main Exposure or Risk Factor	Randomized treatment allocation in original STARRT-AKI trial (accelerated RRT initiation strategy versus standard strategy).
Baseline Characteristics (Table 1 data)	• Age • Sex • Ethnicity • Baseline creatinine • Past medical history (including history of hypertension, diabetes, congestive heart failure, coronary artery disease, and liver disease) • Cardiopulmonary bypass during index admission • SOFA score • Presence of sepsis • Pre-randomization creatinine • Pre-randomization pH • Pre-randomization cumulative fluid balance • Pre-randomization diuretic usage
Covariates	N/A
Outcome(s) Definitions	Outcome definitions unchanged from those of the main STARRT-AKI analysis

Outline of Analysis Plan	
Primary Outcome Variables	All-cause mortality at 90 days after randomization
Secondary Outcome Variables	• Cumulative fluid balance • Discharge disposition • Median number of days receiving mechanical ventilation • Median number of days in the ICU • ICU mortality • RRT dependence at 90 days • Hospital readmission at 90 days • Mortality at 365 days
Detailed Analysis Plan	Descriptive analysis will be performed on baseline demographic and clinical characteristics. Continuous variables will be summarized using means with standard deviation (SD) or medians with interquartile range (IQR), where appropriate. Categorical variables will be summarized using frequency and percentage. Variables with missing data will be excluded from the denominator. Between cohort comparisons (accelerated vs standard therapy) will be examined using standardized mean differences (SMD). SMDs for categorical variables with more than 2 levels will be computed using the multinomial extension of Cohen's. Outcome variables will be examined in a similar fashion, but p-values used to compare results across the two cohorts. Time to event outcomes (90-day and 365-day mortality) will be examined using Kaplan-Meier curves and stratified by cohort type. A log-rank test will be used to compare curves between cohorts. Cumulative net fluid curves will be plot for each group over a 14-day period. Finally, a subgroup analysis of the 90-day time to event outcome will be performed for those with and without cardiopulmonary bypass in the 7 days preceding randomization.
Proposed Tables and Figures	• Table 1: Baseline patient characteristics separated by randomization allocation (accelerated RRT initiation strategy vs. standard strategy) • Table 2: Primary and secondary outcomes separated by randomization allocation (accelerated RRT initiation strategy vs. standard strategy) • Figure 1: Kaplan-Meier curve for 90-day mortality separated by randomized group • Figure 2: Cumulative fluid balance over the 14 days following randomization separated by randomized group • Figure 3: Kaplan-Meier curves for 90-day mortality separated by randomized group for patients that did and did not undergo cardiopulmonary bypass within the 7 days preceding randomization