

PRESERVE

Prevention of Serious Adverse Events Following Angiography



Purpose: A comparison of approaches to prevent adverse events in a patient population at high risk for renal injury following angiography.

Trial Design: Phase 3 interventional, randomized, double-blinded trial. N= 5177. Comparison of IV sodium bicarbonate (1.26%) with IV sodium chloride (0.9%), and oral N-acetylcysteine for 5 days with oral placebo. 2X2 design. 90-day follow-up after angiography.

Primary Endpoints: Adverse events composite @ 90 days after angiography (death, dialysis, declining renal function – serum creatinine increased $\geq 50\%$).

Secondary Endpoint: contrast-associated acute kidney injury (CA-AKI)

	sodium bicarbonate vs. sodium chloride	P value	acetylcysteine vs placebo	P value
Primary Endpoint	4.4% vs 4.7%	0.62	4.6% vs 4.5%	0.88

Conclusion: The trial was stopped after an interim analysis. For adverse events or contrast-associated acute kidney injury with angiography, no benefit was found with IV sodium bicarbonate vs IV sodium chloride, or oral N-acetylcysteine vs placebo.