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Prediction and management of acute kidney injury with explainable artificial intelligence (PRIME): a study protocol for a randomized controlled trial

Giae Yun¹, Jinyeong Yi², Sang Yub Han³, Eun Jeong Kwon¹, Seokwoo Park¹, Jong Cheol Jeong¹, Ho Jun Chin¹, Ki Young Na¹, Jaesik Choi⁴, Sejoong Kim⁵

¹Department of Internal Medicine-Nephrology, Seoul National University Bundang Hospital, Korea, Republic of

²Department of Department of Health Science and Technology, Graduate School of Convergence Science and Technology, Seoul National University College of Medicine, Korea, Republic of

³Department of , Seoul National University College of Medicine, Korea, Republic of

⁴Department of Graduate School of Artificial Intelligence, Korea Advanced Institute of Science and Technology, Korea, Republic of

⁵Department of Center for Artificial Intelligence in Healthcare, Seoul National University Bundang Hospital, Korea, Republic of

Objectives: Acute kidney injury (AKI) is a common but harmful clinical syndrome that requires immediate management. There are many studies on the early detection of AKI, but only some studies have performed management proactively before AKI occurs. We established an artificial intelligence (AI) prediction model through our previous study, and the actual AKI predictive power was about 95%. In this study, we will utilize explainable AI to predict the development of AKI in hospitalized patients and determine whether the incidence of AKI may be decreased by proactively managing risk factors.

Methods: We designed a prospective, investigator-initiated, single-center, single-blinded, randomized controlled study with two experimental groups. A total of 1438 participants with hospitalized patients will be enrolled and randomized into two groups; intervention or usual-care groups. We will apply an AKI prediction model based on the patient's demographic. We will collect data on vital signs, laboratory test results, medication history, and surgical records. We provide information on whether AKI develops within 48 hours and the top 10 explanatory factors for predicting AKI to the physician. Intervention group receives the prediction results daily until the patient is discharged or up to 7 days after admission. Usual-care group does not receive analysis results. Primary outcome is the incidence of AKI. Secondary outcomes include severe AKI (stage 2 or 3), renal replacement therapy, and death during hospitalization. We calculated the required sample size for a two-sided significance level of $\alpha = 0.05$, a power of 80%; thus, determined that 719 participants would be necessary for each group.

Results: The Institutional Review Boards of Seoul National University Bundang Hospital approved this study (No. B-2301-804-301). Patient enrollment will initiate on March 1, 2023.

Conclusions: This study will be the first randomized controlled trial to apply the technology of predicting AKI using Explainable AI to clinical practice in adult inpatients.