The Efficacy of Initial Hemopurification Strategy for Acute Paraquat Poisoning in Adults: Study Protocol for a Randomized Controlled Trial (HeSAPP)

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Statistical analysis

Considering the high cost of each participant, intention to treat (ITT) analysis would be adopted to fully use the data. Drop-out rate, which may increase the bias of ITT analysis, would stay low in this trial with the relatively short course of disease. To obtain a relatively conservative result, the last observation carried forward (LOCF) method would be used to fill up missing and drop out data. The missing data of survival would be carried forward as death, so as to reduce potential treatment effect bias induced by the active arms. Results would be calculated by Statistical Analysis System (SAS) 9.3, and P <0.05 is defined as statistically significant. The Cox regression model (5% significance level) would be applied to examine the relationship between 28-day mortality and intervention group, paraquat ingestion amount, urine dithionite test results, time lapse from intoxication to treatment, age and the acid-base or electrolyte status on admission. For secondary outcome, rate of necessary oxygen uptake and rate of mechanical ventilation, rate of general complications, such as respiratory failure, acute kidney injury (AKI), acute liver failure, pancreas function abnormality and Multiple Organ Failure (MOF), rate of intervention related complications, such as catheter placement related complications, thrombocytopenia and deep venous thrombosis and rate of adverse events, which include unexpected death, severe hemorrhage or edema, unplanned extubation, coagulation in the extracorporeal circulation, blockage of cartridge, incorrect pipe connection, RxC contingency tables would be used to test the difference of these indicators in four groups. If significant differences are found, Bonferroni test would be performed to find treatment effect differences between each group. As for length of stay and scores, one way ANOVA would be applied. Exploratory subgroup analysis would be performed to investigate treatment effect in different patients. Patients would be divided into subgroups by these factors: urine dithionite test result (light blue, navy blue and dark blue), and time from ingestion to treatment (≥4 h and <4 h). The survival time of each group would also be analyzed with the help of log-rank test, Cox regression and Kaplan-Meier survival curve.