

## **A Double-Blind, Randomized, Controlled Trial on N-Acetylcysteine for the Prevention of Acute Kidney Injury in Patients Undergoing Allogeneic Hematopoietic Stem Cell Transplantation**

**Authors :** Sara Ataei, Molouk Hadjibabaie, Amirhossein Moslehi, Maryam Taghizadeh-Ghehi, Asieh Ashouri, Elham Amini, Kheirollah Gholami, Alireza Hayatshahi, Mohammad Vaezi and Ardeshir Ghavamzadeh

**Abstract :** Acute kidney injury (AKI) is one of the complications of hematopoietic stem cell transplantation and is associated with increased mortality. N-acetylcysteine (NAC) is a thiol compound with antioxidant and vasodilatory properties that has been investigated for the prevention of AKI in several clinical settings. In the present study, we evaluated the effects of intravenous NAC on the prevention of AKI in allogeneic hematopoietic stem cell transplantation patients. A double-blind randomized placebo-controlled trial was conducted, and 80 patients were recruited to receive 100 mg/kg/day NAC or placebo as intermittent intravenous infusion from day -6 to day +15. AKI was determined on the basis of the Risk-Injury-Failure-Loss-Endstage renal disease and AKI Network criteria as the primary outcome. We assessed urine neutrophil gelatinase-associated lipocalin (uNGAL) on days -6, -3, +3, +9, and +15 as the secondary outcome. Moreover, transplant-related outcomes and NAC adverse reactions were evaluated during the study period. Statistical analysis was performed using appropriate parametric and non-parametric methods including Kaplan-Meier for AKI and generalized estimating equation for uNGAL. At the end of the trial, data from 72 patients were analyzed (NAC: 33 patients and placebo: 39 patients). Participants of each group were not different considering baseline characteristics. AKI was observed in 18% of NAC recipients and 15% of placebo group patients, and the occurrence pattern was not significantly different ( $p = 0.73$ ). Moreover, no significant difference was observed between groups for uNGAL measures ( $p = 0.10$ ). Transplant-related outcomes were similar for both groups, and all patients had successful engraftment. Three patients did not tolerate NAC because of abdominal pain, shortness of breath and rash with pruritus and were dropped from the intervention group before transplantation. However, the frequency of adverse reactions was not significantly different between groups. In conclusion, our findings could not show any clinical benefits from high-dose NAC particularly for AKI prevention in allogeneic hematopoietic stem cell transplantation patients.

**Keywords :** acute kidney injury, N-acetylcysteine, hematopoietic stem cell transplantation, urine neutrophil gelatinase-associated lipocalin, randomized controlled trial

**Conference Title :** ICSRD 2020 : International Conference on Scientific Research and Development

**Conference Location :** Chicago, United States

**Conference Dates :** December 12-13, 2020