Article (3)

Safety and efficacy of autologous non- hematopoietic enriched stem cell nebulization in COVID-19 patients: a randomized clinical trial, Abu Dhabi 2020

Abstract:

Background: The novel SARS-CoV-2 has caused the coronavirus disease 2019 (COVID-19) pandemic. Currently, with insufficient worldwide vaccination rates, identifying treatment solutions to reduce the impact of the virus is urgently needed. **Method:** An adaptive, multicentric, open-label, and randomized controlled phase I/II clinical trial entitled the "SEN- TAD-COVID Study" was conducted by the *Abu Dhabi Stem Cells Center* under exceptional conditional approval by the Emirates Institutional Review Board (IRB) for COVID-19 Research Committee from April 4th to July 31st, 2020, using an autologous peripheral blood non-hematopoietic enriched stem cell cocktail (PB-NHESC-C) administered by compressor (jet) nebulization as a complement to standard care therapy. The primary endpoints include safety and efficacy assessments, adverse events, the mortality rate within 28 days, and the time to clinical improvement as measured by a 2-point reduction on a seven-category ordinal scale or discharge from the hospital whichever occurred first. **Results:** The study included a total of 139 randomized COVID-19 patients, with 69 in the experimental group and 70 in the control group (standard care). Overall survival was 94.20% for the cocktail-treated group vs. 90.27% for the control group. Adverse events were reported in 50 (72.46%) patients receiving PB-NHESC-C and 51 (72.85%) in the control group ($p = 0.9590$), with signs and symptoms commonly found in COVID-19. After the first 9 days of the intervention, 67.3% of cocktail-treated patients recovered and were released from hospitals compared to 53.1% (RR = 0.84; 95% CI, 0.56–1.28) in the control group. Improvement, i.e., at least a 2-point reduction in the severity scale, was more frequently observed in cocktail-treated patients (42.0%) than in controls (17.0%) (RR = 0.69; 95% CI, 0.56–0.88). **Conclusions:** Cocktail treatment improved clinical outcomes without increasing adverse events. Thus, the nebulization of PB-NHESC-C was safe and effective for treatment in most of these patients. **Trial registration:** ClinicalTrials.gov. NCT04473170. It was retrospectively registered on July 16th, 2020.