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Título	Bone marrow mesenchymal cells for adult COVID-19 in mechanical ventilation due to SARS: a safety and feasibility clinical study
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Justification: Severe Acute Respiratory Syndrome (SARS) due to COVID-19 has caused millions of deaths. Some previous studies have shown that advanced therapy using Mesenchymal Stromal Cells (MSC) and its immunomodulatory properties could be a potential therapeutic strategy to block pulmonary inflammation. This clinical study was elaborated to evaluate the MSC adoptive immunotherapy as adjuvant therapy for SARS caused by COVID-19. **Objective:** The primary endpoint was to define safety and feasibility of allogeneic bone marrow (BM) MSC immunotherapy in patients with SARS due to COVID-19. The secondary endpoints were to monitor treatment response by time to SARS resolution according to PaO₂/FiO₂ ratio (P/F ratio) variations; to verify C-reactive protein (CRP) serum variation and flow cytometric analysis of peripheral blood leukocytes immune profiling of the patients. **Methods:** BM MSC were obtained from the BM collection bag/filter cellular residues and expanded *ex vivo* up to the second passage. Two infusions of 1x10⁶ BM-MCS cells/kg were administered between 72 to 96 hours after mechanical ventilation was started. Patients were continuously monitored during the infusion procedure and for 30 days after the infusions to evaluate clinical and laboratory changes according to predetermined parameters. **Results:** Between October 2020 and January 2021, eight patients under invasive mechanical ventilation were enrolled. No adverse events were associated with the infusion. Six patients (75%) have increased clinical-laboratory parameters, being cured from SARS by reaching P/F ratio over 300 in a median of 5,5 days. Among the responders there was one patient with advanced liver disease that died of liver failure after ICU discharge. Treatment was followed by a decreased tendency in CRP serum and T lymphocytes increased in the responders. **Conclusion:** In view of its safety and feasibility the immunotherapy using BM-MSC might be considered an alternative to COVID-19 infected patients developing SARS.