

Efficacy of a Low Dose of Melatonin as an Adjunctive Therapy in Hospitalized Patients with COVID-19: A Randomized, Double-blind Clinical Trial

Gholamreza Farnoosh¹, Mostafa Akbariqomi¹, Taleb Badri¹, Mahdi Bagheri¹, Morteza Izadi¹, Ali Saeedi-Boroujeni², Ehsan Rezaie¹, Hadi Esmaeili Gouvarchin Ghaleh¹, Hossein Aghamollaei¹, Mahdi Fasihi-ramandi¹, Kazem Hassanpour³, and GholamHossein Alishiri¹

¹Baqiyatallah University of Medical Sciences

²Ahvaz Jundishapur University of Medical Sciences

³Sabzevar University of Medical Sciences

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Abstract

Abstract Aim: To evaluate the clinical efficacy of adjuvant use of melatonin in patients with coronavirus disease 2019 (COVID-19). **Methods:** This single-center, double-blind, randomized clinical trial included 74 hospitalized patients with confirmed mild to moderate COVID-19 at Baqiyatallah Hospital in Tehran, Iran, from April 25, 2020 to June 5, 2020. Patients were randomly assigned in a 1:1 ratio to receive standard of care and standard of care plus melatonin at a dose of 3 mg three times daily for 14 days. Clinical characteristics, laboratory, and radiological findings were assessed and compared between two study groups at baseline and post-intervention. Safety and clinical outcomes were followed up for four weeks. **Results:** A total of 24 patients in the intervention group and 20 patients in the control group completed the treatment. Compared with the control group, the clinical symptoms such as cough, dyspnea, and fatigue, as well as the level of CRP and the pulmonary involvement in the intervention group had significantly improved ($P < 0.05$). The mean time of hospital discharge of patients and return to baseline health was significantly shorter in the intervention group compared to the control group ($P < 0.05$). No deaths and adverse events were observed in both groups during this study. **Conclusions:** Adjuvant use of melatonin has a potential to improve clinical symptoms of COVID-19 patients and contribute to a faster return of patients to baseline health. **Keywords:** COVID-19, Melatonin, Clinical trial, Adjunctive therapy Trial Registration: ClinicalTrials.gov Identifier: NCT04409522

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