Efficacy and safety of polyherbal formulation as an add-on to the standard of care in mild to moderate COVID-19: A randomized, double-blind, placebo-controlled trial

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Background: Novel corona virus disease 2019 (COVID-19) pandemic is a significant contributor to morbidity and mortality in affected individuals. Modulating the immune response in COVID-19 is now an established treatment approach. Herbal formulations have long been assessed for their potential immune modulating effects. As the search for potential antiviral and immune modulating therapy for COVID-19 is ongoing,this polyherbal formulation could be potentially beneficial. Referenced evidences for using these formulations in humans as justification are as hereunder;

Objective: To assess the efficacy and safety of polyherbal formulation (designated as IP) in comparison to placebo as add on to the standard of care (SoC) among patients with mild to moderate novel corona virus disease 2019 (COVID-19)

Methods: Hospitalized RT-PCR positive patients of mild to moderate COVID-19 disease were randomized to either placebo or IP as an add-on to SoC. The polyherbal formulation (IP) was standardized as per Guidelines for Drug Development of Ayurvedic formulations (CCRAS, AYUSH Govt.of India) and Consort guidelines for reporting randomized controlled trials for Herbal medicine intervention. Using validated quantitative reverse transcription-polymerase chain reaction (qRT-PCR), we assessed the effect on viral load (VL). Changes in immunological parameters such as blood lymphocyte subset and serum immunoglobulin were determined. The clinical improvement was assessed using a numerical rating scale (NRS) and WHO ordinal scale. Patients were followed for 30 days after randomization.

Results: In total, 72 patients were randomized to either placebo (n=33) and IP (n=39). Fifty-two patients (n=21 in placebo and n=31 in IP arm) had qRT-PCR on day 0 and day 4. There was significant reduction in VL in IP arm (from 662081 copies/mL on day 0 to 48963 copies/mL on day 4; p=0.002)) but not in the placebo arm (from 385670 copies/mL on day 0 to 66845 copies/mL on day 4, p=0.106). Change in the NRS score and WHO ordinal scale score was significant in both treatment arms. However, the difference between the two arms was statistically significant in favour of drug arm. The increase in Th1 response was significant in the IP arm (p=0.023) but not in the placebo arm (p=0.098), thus implying immunomodulatory activity in the drug. The Covid specific antibodies were seen in either arm, though there was no statistical difference, numerical values were higher in the IP arm. No safety concerns were observed in any of the trial participants.

Conclusion: This study finds that polyherbal formulation significantly reduces viral load and contributes to immunomodulation and improvement in clinical conditions and early recovery when used as add-on to the standard care in patients with mild to moderate COVID-19 without any side effects. It reflects that the polyherbal formulation has enhancing effect on SoC.

Biography

Suresh Patankar has a long and sustained record of research in both modern and traditional systems of medicine. His extensive clinical work has leveraged the continued research and innovations that he has so tirelessly conducted during more than last three decades. His interest in the domain of herbal or phytoformulations has resulted in several newer herbal formulations useful in disorders which have little help in the modern medicine. His interests in technological innovations have lead to the development of surgical instruments for laparoscopy that have the potential to change the modalities of laparoscopy in future. Apart from research activities he has immensely contributed to the state medical education system and effected noteworthy reforms in it. He is a strong advocate and promoter of holistic health through the integrative application of several systems of medicine apart from being a well known surgeon reputed for his extensive skills.

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