

Efficacy and Safety of Ayush-64 as standalone or adjunct to standard care in COVID-19: A Structured Summary of Protocol for a Systematic Review

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Abstract

Background: Apart from vaccines, significant efforts have been made to develop prophylactic and therapeutic interventions against COVID-19. Lack of standard therapeutic options for the management of COVID-19 contributes to seriousness of this novel disease. The current strategy for exploring therapeutic interventions to manage this pandemic is broadly based on repurposing and repositioning of existing medications and recommending them for symptomatic support. In the early stage of COVID-19, the interventions that limit the progression of the disease and facilitate early recovery may play a significant role. AYUSH-64 is a polyherbal Ayurveda formulation developed by the CCRAS, Ministry of Ayush, Government of India. It has been found effective and safe in various infective febrile conditions like malaria, microfilaremia, chikungunya, and influenza [1-5]. AYUSH-64, was repurposed for the management of asymptomatic and mild to moderate COVID-19 based on the experimental and clinical outcomes indicating its potential benefits and safety in disease conditions like influenza-like illness. Government of India recommended the use of AYUSH-64 to manage the asymptomatic and mild COVID-19 cases on the basis of outcomes of clinical studies on AYUSH-64 in COVID-19 [6,7]. In this context, this systematic review is planned to synthesize evidence related to the safety and efficacy of AYUSH-64 as standalone or adjunct to standard care in managing asymptomatic and mild to moderate COVID-19.

Methods: The PRISMA-P (Preferred Reporting Items for Systematic Reviews and Meta-analyses- Protocol statement) guidelines have been followed for drafting this protocol. All Randomized Controlled trials that assess the efficacy and safety of AYUSH-64 for the management of COVID-19 as standalone or adjunct to conventional standard care will be considered for this systematic review. Comprehensive search will be done for the published studies as per the pre-designed search strategy in the electronic databases such as AYUSH Research Portal's "National Repository on AYUSH COVID-19 Clinical and Other R&D Initiatives", PubMed, Cochrane Central Register of Controlled Trials, DHARA, IndMED, COVID-19 Evidence Alerts from McMaster PLUSTM, Epistemonikos, TRIP database, Google Scholar, National Collaborating Centre for Methods and Tools database of COVID-19 studies, Clinical Trial Registry of India and WHO dashboard for clinical trials related to COVID-19 from inception till October 2021. Data selection and extraction for each study will be performed independently by two review authors, with disagreements resolved by discussion with third review author/consensus. Risk of bias assessment will be performed using the revised tool to assess the risk of bias in randomized trials (RoB 2). The results will be quantitatively synthesized (meta-analysis) using Review Manager 5.4. If meta-analysis will not be conducive due to substantial heterogeneity, we will summarize and explain the results of the included studies as the systematic qualitative synthesis.

Discussion: To date, this will be the first systematic review on the Ayurveda intervention, AYUSH-64 that will synthesize the evidence on its efficacy and safety in the management of COVID-19. The pilot search undertaken before planning this systematic review resulted in 07 clinical studies on AYUSH-64 that evaluate its efficacy and safety in the management of COVID-19. These search results justify the initiation of this systematic review. This systematic review will help the policy makers for its wider

implementation in the management of asymptomatic and mild to moderate COVID-19. The results of this systematic review will be published in an indexed open-access journal to ensure wider dissemination.

Declarations

Funding: This systematic review is not funded by any organization.

Study registration: Registered with PROSPERO (CRD42021267844) dated 14.07.2021

Full protocol: The full protocol is enclosed as an additional file, accessible from the Journal website (Additional file 1). This communication serves as a summary of the key elements of the full protocol.

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Authors' contributions

Review question, search strategy and first draft of the protocol was designed by AKR, AA, KK and PM, protocol was refined by BY and SK and approved by BCR and NS. AKR, PM, AA wrote the first draft of this manuscript and further refined by BY, SK, BCR and NS. All the authors participated in the idea refining, revising the manuscript for important intellectual content, and approved the final version submitted for publication.

Availability of data and materials

Not applicable

Ethics approval and consent to participate: Ethics approval is not required for systematic review.

Consent for publication: Not applicable.

Competing interests: The authors declare that they have no competing interests.

References

1. Gundeti MS, Bhurke LW, Mundada PS, Murudkar S, Surve A, Sharma R, *et al.* AYUSH 64, a polyherbal Ayurvedic formulation in influenza like illness: Results of a pilot study. *J Ayurveda Integr Med.* 2020 May 14:S0975-9476(20)30025-5. doi: 10.1016/j.jaim.2020.05.010.
2. Bhatia D. Role of AYUSH64 in malaria epidemic. *J Res Ay Sid* 1997;18:716.

3. Chari MV, Venkataraghavan S, Seshadri C, Shetty BR, Gowri N. A double blind clinical trial with ayush64 an ayurvedic drug in *P. vivax* malaria. J Res Ay Sid 1982;6:10516.
4. Pandey PN, Kishore P. Effect of Ayush64 and saptaparnaghanavati on microfilaraemia. J Res Ay Sid 1989;12:14550.
5. Anonymous. Management of Chikungunya through Ayurveda and Siddha – A Technical Report. Central Council for Research in Ayurvedic Sciences, Department of AYUSH, Ministry of Health & Family Welfare, Govt. of India; 2009.
6. Kotecha R. The journey with COVID-19: Initiatives by Ministry of AYUSH. J Ayurveda Integr Med. 2021 Jan-Mar;12(1):1–3. doi: 10.1016/j.jaim.2021.03.009.
7. Ministry of AYUSH, Govt. of India. National Clinical Management Protocol based on Ayurveda and Yoga for management of Covid19. Available from: <https://www.ayush.gov.in/docs/ayushProtocolcovid19.pdf>; 2020. [Last accessed on 2021 Nov 12].

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