

24-Week Clinical Trial Finds No Evidence of Liver or Kidney Injury with Standardised Ashwagandha Root Extract

Multicentre randomised placebo-controlled trial involving 1,200 vaccinated adults finds Ashwagandha root extract well tolerated over 24 weeks; study published recently in *Frontiers in Medicine*

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A large multicentre clinical study published recently in *Frontiers in Medicine* has found that daily administration of a standardised Ashwagandha root extract for 24 weeks was well tolerated, with no evidence of treatment-related liver or kidney injury.

Published on 20 August 2026, (*Front. Med.*, Vol 13, 20 August 2026. <https://doi.org/10.3389/fmed.2026.1852954>) the study, titled “**Safe prolonged prophylactic use and tolerability of Ashwagandha following COVISHIELD™ vaccination over 24 weeks: a multicentre randomised double-blind placebo-controlled trial,**” was conducted by a multidisciplinary team of researchers from 09 institutions, including the Central Council for Research in Ayurvedic Sciences (CCRAS), All India Institute of Ayurveda, National Institute of Ayurveda, Jaipur, Ayush Centre of Excellence, Translational Health Science and Technology Institute, Centre for Complementary and Integrative Health, and Interdisciplinary School of Health Sciences, Savitribai Phule Pune University, among others.

The study was conducted by a multidisciplinary group of 45 researchers from 9 institutions, bringing together expertise across Ayurveda, clinical medicine, rheumatology, complementary and integrative health and related disciplines. The randomised, double-blind, placebo-controlled trial included 1,200 apparently healthy adults aged 18–70 years who had received a first, second or booster dose of COVISHIELD vaccine. Participants were randomly assigned to receive either 500 mg of a standardised aqueous Ashwagandha root extract daily, equivalent to 4 grams of raw root powder, or a matching placebo. The study was conducted across seven study sites in India and included clinical, laboratory and immunological assessments. The trial was registered with the Clinical Trials Registry–India (CTRI/2021/06/034496).(<http://www.clinicaltrials.gov>)

Participants received the intervention for 24 weeks and were followed through week 28. Of the 1,200 participants enrolled, 1,032 (86%) completed the study.

The study found a favourable safety and tolerability profile for the standardised Ashwagandha root extract over the 24-week intervention period. Liver and kidney function parameters remained within the reported reference ranges, with assessments including liver enzymes, bilirubin, creatinine and blood urea showing no evidence of treatment-related hepatic or renal injury.

No serious adverse events were considered attributable to the study intervention, and no participant withdrew from the trial because of an adverse event.

Vaidya Rajesh Kotecha, Secretary, Ministry of Ayush, emphasised that the findings contribute to the robust scientific evidence supporting the safety and appropriate use of standardised Ayurveda interventions. He observed, “High-quality clinical research strengthens the scientific evidence-base of Ayurveda and contributes to a deeper understanding of its potential within contemporary healthcare. The growing body of evidence from rigorous clinical studies is also supporting the responsible global utilisation of Ayurveda and its interventions across health and wellness settings.”

Dr. Arvind Chopra, Ayush Distinguished Scientist Chair and Director & Chief Rheumatologist at the Centre for Rheumatic Diseases, Pune, India, and lead author of the study, highlighted the significance of the findings, stating, “This large, multicentre, randomised clinical trial provides important evidence on the safety and tolerability of standardised Ashwagandha over 24 weeks. Throughout the study, liver and kidney function parameters remained within physiological reference ranges, with no treatment-related liver or kidney injury observed. The study also demonstrated that Ashwagandha did not interfere with vaccine-induced immunity, with high levels of neutralising activity maintained across both the Ashwagandha and placebo groups. These findings reinforce the importance of evaluating standardised Ayurvedic preparations through rigorous, well-controlled clinical research.”

Prof. Bhushan Patwardhan, National Professor of Ayush and co-author of the study, emphasised the significance of generating high-quality evidence for Ayurveda. “This study is an important example of how Ayurveda can be evaluated through robust, contemporary clinical research without losing sight of its traditional foundations. The favourable safety and tolerability findings over 24 weeks add to the clinical evidence on standardised Ashwagandha preparations and underline the importance of evidence-based approaches for their responsible integration into healthcare.”

Prof. (Vaidya) Rabinarayan Acharya, Director General, Central Council for Research in Ayurvedic Sciences (CCRAS), emphasised the importance of generating robust clinical evidence for Ayurvedic interventions, stating, “The findings of this multicentre clinical trial provide valuable evidence on the safety and tolerability of a standardised Ashwagandha root extract when administered under controlled conditions for 24 weeks. Such well-designed clinical studies are important for strengthening the scientific evidence base of Ayurveda and for supporting the responsible and evidence-informed use of standardised Ayurvedic preparations.”

The study also assessed the effect of 24-week administration of the standardised aqueous Ashwagandha root extract on the immune response following COVISHIELD vaccination. Virus-neutralising activity exceeded 85% in both the Ashwagandha and placebo groups, with no statistically significant difference between the groups.

The findings contribute to the clinical evidence base on standardised Ashwagandha preparations and reinforce the importance of robust clinical research in supporting their safe and evidence-informed use.

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