

## The Lancet publishes Ph I trial studies of Covaxin

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### Bharat Biotech announces Indian innovation international validation



Following the speculations regarding the efficacy of its COVID-19 vaccine, Hyderabad based Bharat Biotech has recently announced the publication of the phase 1 clinical trials of Covaxin in the most prestigious medical journal of The Lancet Infectious diseases.

This is the first clinical trial publication on a COVID-19 vaccine from India.

The study reveals that the vaccine was well tolerated in all dose groups with no vaccine-related serious adverse events. The most common adverse event was pain at the injection site, followed by headache, fatigue, and fever. The overall incidence of solicited local and systemic adverse events in this study was 14–21% in all vaccine-treated groups, which is noticeably lower than the rates for other SARS-CoV-2 vaccine platform candidates and similar to the rates for other inactivated SARS-CoV-2 vaccine candidates.

One serious adverse event (positive for SARS-CoV-2 by a nucleic acid test) in an individual was not related to vaccination. Because the event occurred in the 5 days after vaccination, the development of a protective immune response was not likely.

"We continue in this journey of bringing you work that is made in India on par with international standards", says Suchitra Ella, Joint Managing Director, Bharat Biotech, Hyderabad.