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Covaxin phase 3 trial shows vaccine has 78% efficacy

The analysis was on a data set of 127 positive volunteers

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NEW DELHI

The efficacy of Covaxin has dropped a tad lower to 78% from the 81% reported in March.

On Wednesday, Bharat Biotech, in a press release, announced results from an interim analysis of its phase 3 trial. The efficacy against severe COVID-19 disease was 100%, the company said, but that against protecting from asymptomatic COVID-19 infection was 70%.

The analysis was on a data set of 127 COVID-19 positive volunteers.

Efficacy, a measure of risk reduction from a vaccine, varies among vaccines commercially available. Ranking by reported efficacy gives relative risk reductions of 95% for Pfizer-BioNTech vaccine, 94% for the Moderna shot, 90% for Sputnik V, and 67% each for the J&J and AstraZeneca-Oxford vaccines, according to a review article in the *Lancet Microbe*.

The safety and efficacy results from the final analysis will be available in June, and the final report will be submitted to a peer-reviewed publication. "Based on the achievement of the success criteria, placebo recipients have now become eligible to receive two doses of Covaxin," Bharat Biotech said in a statement.

In a press briefing on Wednesday, Balram Bhargava, Director-General, ICMR, furnished data to show that four in 10,000 of those who had been inoculated with Covaxin went on to test positive.

"Even if it had been five or 10 per 10,000, it wouldn't be a cause for worry because the objective of the vaccine is to protect against severe disease, and we have demonstrated that in protecting against severe disease it is 100%," a senior scientist from Bharat Biotech, who declined to be identified, told *The Hindu*.

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The vaccine had been tested against emergent international variants of concern, such as the U.K. strain and the Indian B.1.617 strain, the scientist said. "Because the vaccine produces a very broad range of antibodies, unlike many other vaccines that are solely directed at the spike protein, it does a great job at neutralising the various." The company has reported efficacy against the U.K. variant in a peer reviewed journal (*Journal of Travel Medicine*) but is yet to publicise results on the vaccine's efficacy against the Brazilian strain.

"Covaxin has been found to effectively neutralise the double mutant variant as well," the ICMR tweeted on Wednesday.

Krishna Ella, chairman and managing director, Bharat Biotech, said, "Efficacy against SARS-Cov-2 has been established. Covaxin has demonstrated an excellent safety record in human clinical trials and in usage under emergency use. Covaxin is now a global innovator vaccine derived from Research and Development from India. "The efficacy data against severe COVID-19 and asymptomatic infections is highly significant, as this helps reduce hospitalisations and disease transmission, respectively."

The phase 3 study enrolled 25,800 participants in the age group of 18-98, including 2,433 above 60 and 4,500 with comorbidities. The primary endpoint of phase 3 clinical trial is based on the first occurrence of PCR-confirmed symptomatic (mild, moderate, or severe) COVID-19 with onset at least 14 days after the second study vaccination in serologically negative (to SARS-CoV-2) adult participants at baseline.