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Short Communication

Clinical Trails Performed on Covaxin During COVID-19 Pandemic

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DESCRIPTION

Covaxin (BBV152) is a COVID-19 vaccine based on a whole inactivated virus developed by Bharat Biotech in collaboration with the Indian Council of Medical Research-National Institute of Virology.

Effectiveness and efficacy

A vaccine is considered effective if the estimate is 50% with a lower limit of the 95% confidence interval greater than 30%. [1] Effectiveness is expected to gradually decline over time.

The vaccine was found to be 64% (95% CI, 29-82%) effective against asymptomatic cases, 78% (65-86%) effective against symptomatic disease, 93% (57-100%) effective against severe disease, and 65% (33-83%) effective against the Delta variant in a phase 3 clinical trial with 25,798 participants [2].

Clinical trials

Phase I and II trials: The Indian Council of Medical Research's (ICMR) National Institute of Virology approved and provided virus strains for the development of a fully indigenous COVID-19 vaccine in May 2020.The Drugs Controller General of India (DCGI), Government of India, granted the company permission to conduct Phase I and Phase II human trials of a developmental COVID-19 vaccine codenamed BBV152 in June 2020.

The Indian Council for Medical Research chose 12 sites for Phase I and II randomized, double-blind, placebo-controlled clinical trials of vaccine candidates [3].

The Phase I trial results were published in The Lancet in January 2021.

The Phase II results were published in The Lancet on March 8, 2021. Due to the difference in dosing regimes between Phase I and Phase II trials, the study found that Phase II trials had a higher immune response and induced T-cell response. Doses in Phase II were given every four weeks, as opposed to every two weeks in Phase I. The vaccine's neutralisation response was found to be significantly higher in Phase II.

Phase III trials: Covaxin received approval to conduct Phase III human trials in November 2020, following the completion of Phase I and II. A randomised, double-blind, placebo-controlled study among volunteers aged 18 and up, it began on November 25 and involved approximately 26,000 volunteers from 22 sites across India. The refusal rate for Phase III trials was significantly higher than for Phase I and Phase II trials. As a result, only 13,000 volunteers had been recruited by the 22nd of December, with the figure rising to 23,000 by the 5th of January.

Multiple ethical violations have been reported at one of their trial sites in Bhopal, potentially lowering the overall data quality.

Us immunobridging and booster phase II/III Trial

Ocugen registered a Phase 2/3 trial for 400 people in the United States in March 2022 to compare immune responses to those in the Indian phase 3 trials, as well as safety and tolerability. The trial will also evaluate the vaccine as a booster after other Covid vaccines used in the United States. In April 2022, Ocugen halted Covaxin's bridging trial citing WHO inspection results.

Phase IV trials: Bharat Biotech announced the start of phase IV trials in June 2021 to assess the vaccine's real-world effectiveness. A study of effectiveness and hesitancy in healthcare workers at the Max Group of Hospitals in New Delhi is currently being tested by Covaxin and Covishied [4].

Trials on minors: The Drugs Controller General of India (DCGI) approved clinical trials for children aged 2 to 18 in May 2021. The trials are taking place at AIIMS Delhi and Patna. At the AIIMS Patna, 54 children had registered. According to clinical trial data, 525 people are enrolled in the study.

CONCLUSION

Bharat Biotech's Covaxin (codenamed BBV152) is a whole inactivated virus-based COVID-19 vaccine. A phase 3 clinical trial with 25,798 participants discovered that the vaccine is 64% effective against asymptomatic cases (95% CI, 29-82%). Covaxin was granted permission to conduct Phase III human trials in November 2020. A randomised, double-blind, placebo-controlled study was conducted on volunteers aged 18 and up.

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For this phase, approximately 26,000 volunteers were recruited from 22 different locations in India.

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