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## India: Doctors call for investigation into allegations of ethical abuse in covid-19 vaccine trial

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Multiple health groups in India have called for an investigation into allegations of ethical violations during a clinical trial of a covid-19 vaccine developed jointly by India's Bharat Biotech and the Indian Council of Medical Research.

In a statement released on 14 January, groups of doctors and health rights advocates asked the Indian government to halt the trial at the People's Hospital in Bhopal, exclude any data from the site during trial analysis, and take action against those responsible for violations.

The Bharat Biotech vaccine is among two covid-19 vaccines granted accelerated approval on 3 January by India's drug regulatory authority for restricted emergency use, relying on safety and immunogenicity data without efficacy data.<sup>1</sup>

India has also approved the Oxford AstraZeneca vaccine, after reviewing safety, immunogenicity, and efficacy data from outside India and safety and immunogenicity data in India. A trial to evaluate the efficacy of the Bharat Biotech vaccine has enrolled 25 800 participants at 25 sites in 12 cities.

Seven participants enrolled in the trial by the People's Hospital have claimed that they were not informed that they would receive either a vaccine or a placebo. In testimonies at a press conference on 10 January, the participants said that they were told that they would receive a vaccine that would protect them from the novel coronavirus and had been paid Rs750 (£7.5; €8.6; \$10.3) to have the injections.

The All India Drug Action Network, the Forum for Medical Ethics, and the Jan Swasthya Abhiyan (People's Health Movement India), among other groups, have said the participants' testimonies have suggested that trial staff at the site violated the requirements of full disclosure of trial objectives.

The groups said, "The testimonies demonstrate inducement which represents a breach of the tenet of voluntary participation without inducement or coercion. Many participants were misled to enrol in the trial, their vulnerabilities preyed upon."

Responding to the allegations, Bharat Biotech said in a statement that the trial is in full compliance with "good clinical practice guidelines and all regulatory provisions that apply to the conduct of clinical trials in India." The company also said Indian guidelines provide for reimbursement to participants for travel to the trial site and for the daily wage lost as a result of their participation. The payment of Rs750 was offered at all sites and was "not an inducement."

However, the health groups argue that given the "extreme economic vulnerability" of the participants,

which had been exacerbated by the months long lockdown, the payment served as an inducement.

Several participants have also claimed that they were not informed that they were entitled to free medical management if they developed any illness or adverse effects after the injections. The dean of the People's Hospital Anil Dixit denied the allegations. He told *The BMJ*, "This is not correct, we have followed all the requirements for clinical trials."

Signatories on the health groups' statement have said they are concerned about the government's silence on the allegations and the death of one of the participants at the site on 21 December.

Amar Jesani, a physician researcher and the editor of the *Indian Journal of Medical Ethics* told *The BMJ*, "As citizens, we can only raise our concerns with the government. Anyone could make mistakes, but they need to be acknowledged and rectified."

The hospital and Bharat Biotech have said a review and a post-mortem had found that the participant had died from poisoning and police are investigating the death. The company has asserted that the death had no connection with the vaccine.

Jesani and others believe the government's silence is likely driven by a desire to roll out the vaccination campaign as early as possible without interruptions. Sourirajan Srinivasan, a signatory and member of the All India Drug Action Network, told *The BMJ*, "They seem to want to push any problem under the carpet."

The Indian government has ordered 11 million doses of the Oxford AstraZeneca vaccine, manufactured by the Serum Institute of India, and 5.5 million doses of the Bharat Biotech vaccine, to start a campaign to vaccinate around 30 million healthcare and public workers on 16 January.

<sup>1</sup> Covid-19: Indian health officials defend approval of vaccine. *BMJ* 2021;372:n52.pmid: 33414156