



India begins COVID-19 vaccination amid trial allegations

Trial participants in Bhopal say that they could not read consent forms and have not been able to report adverse events. Anoo Bhuyan reports from Bhopal.

Ramesh, a 57-year-old resident of Bhopal in Madhya Pradesh, India, sits outside a tea stall, rummaging inside a dirty bag of crumpled medical documents. He is searching for a record from a nearby private hospital, where he had taken part in a clinical trial for a COVID-19 vaccine in India. He finally finds it. It shows that he received his first injection on Dec 7.

"I went to the nearby hospital in December and was given an injection. I was told it is the COVID-19 vaccine", said Ramesh. "I did not know it was a trial. The people at the hospital did not give me any time to see what I was told to sign. I did not know that I could refuse the injections."

Ramesh is one of several people living in low-income areas in Bhopal who took part in the COVID-19 vaccine trial run by Bharat Biotech, which is developing a vaccine in partnership with the Indian Council of Medical Research, the Indian Government's agency for scientific research. The vaccine is called COVAXIN.

In January, 2021, India's drug regulator issued a restricted emergency approval for COVAXIN, alongside COVISHIELD (the Oxford–AstraZeneca developed vaccine that is also made in India). On Jan 16, 2021, India began the world's largest vaccination programme for COVID-19, targeting an initial group of 300 million people.

Many residents recount how a vehicle with a loudspeaker had come around their neighbourhood in December, 2020. The residents allege that the announcement was made that anyone who came to the nearby People's University private hospital could get a COVID-19 vaccine and 750 INR (£7.50). This hospital was one of the sites conducting the COVAXIN trial. Many locals have been unemployed over the past year and children have been out

of school because of the pandemic, so the small sum of money was attractive enough for them to take part in the trial.

Several participants said that they are illiterate, and thus could not read the consent forms that they signed. Some, like Ramesh, allege that not much was explained to them verbally either, including the fact that this was

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a clinical trial and that they would be given either a vaccine candidate or a placebo, that they might have adverse events following the trial, and that they would be entitled to medical care or compensation if the adverse events were serious.

Many participants such as Jai Ram, a carpenter, have had difficulty reporting adverse events. "I felt quite weak after taking the injection for many days. I did not know what to do but someone advised me to drink juice made from ginger and so I did that", said Ram. Because he does not have a phone, he said that he had not spoken with anyone from the hospital, and thus his complaint of feeling weakness would not be recorded as an adverse event.

Indian rules on clinical trials recognise that sometimes participants might be from marginalised socioeconomic backgrounds, and so the process of taking their informed consent must be lengthy and rigorous. The rules specify that trial ethics committees should ensure that the rights of such people are especially protected and participant's informed consent is recorded on audio and video. For those unable to read and write, an impartial witness should be present.

"There was a videographer in the room who took audio-video recordings of the informed consent",

said A K Dixit, the dean of People's University. However, both Ramesh and Ram said that they did not see anyone recording their consent.

The COVAXIN trial was not paused despite the alleged death of a participant. In an official statement, Bharat Biotech has said that the participant had died 9 days after taking part in the trial. The post-mortem report says that the person had died from a "suspected poisoning". The company's statement says that their own investigation has concluded that the death was "not related to vaccine or placebo". AstraZeneca and Johnson & Johnson both paused their trials last year for safety reviews and investigations when participants reported adverse events.

COVAXIN's approval in India came before the company had finished recruiting for the drug's phase 3 trial. Given that there is no efficacy data for COVAXIN yet, some health workers "may not have confidence in COVAXIN and that is understandable", said Vineeta Bal, immunologist and visiting faculty at the Indian Institute of Science Education and Research, Pune. "The government needs to put out all data, including for efficacy, for the sake of transparency and for building confidence of the people", she said.

"The lack of data for COVAXIN leaves those who have been given it in an uncertain position regarding their status. The vaccine may work out to be safe and efficacious, but that would be owed more to good luck than to good government policy", said Jammi Nagaraj Rao, a public health physician and epidemiologist.

Bharat Biotech and the Indian Council of Medical Research have not responded to requests for comment.

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