A volunteer receives a shot in a trial for Covaxin, a COVID-19 vaccine being developed by Bharat Biotech in collaboration with the Indian Council of Medical Research, during the Phase three trial at the People's Medical College in Bhopal on 7 December 2020. SANJEEV GUPTA/EPA

COVID-19

(/covid-19)

According to several residents in Bhopal, the People's College of Medical Sciences and Research Centre recruited them to participate in the clinical trial of a COVID-19 vaccine without giving them requisite information. Phase three human trials for Covaxin—a COVID-19 vaccine developed by Bharat Biotech, a vaccine manufacturer in Hyderabad—are underway across India. All the trial participants in Bhopal that *The Caravan* spoke to mentioned that representatives of the centre had visited their neighbourhoods looking for volunteers. Some of these residents said they were told that they would get Rs 750 for their time and participation. Some said that they were not told that it was a clinical

trial or informed of possible side effects. Seven people told me that they reported serious adverse events after participating in the trial. Most of them are from families that struggle financially and live close to the Union Carbide plant, which was the source of a fatal gas leak in 1984. Some of the trial participants are also survivors of this industrial accident.

Among the participants was Jitendra, a 36-year-old resident of Shankar Nagar area. Jitender said he went to the People's College of Medical Sciences and Research Centre on 10 December 2020. He said that earlier that day, workers from the college had come to his neighbourhood and made an announcement saying that people would be given a vaccine and some money. "At that time, I just knew they were vaccinating people against COVID-19, and will pay each participant Rs 750, so I thought what's the harm in going? They took care of the commute to and from the hospital as well," he said.

When he reached the hospital, he was told that the vaccine being offered was under trial. Jitendra was enrolled in a phase three trial of Covaxin. On 3 January, the Drug Controller General of India, VG Somani, approved Covaxin for "restricted use in emergency situation." Many public health experts, scientists and activists, questioned this approval as its phase three trial had not been completed and no interim phase three data for it has been published.

While enrolling himself, Jitendra said he informed the trial investigators that he had recently recovered from typhoid and had a persistent cold and cough the past year. The investigators assured him that taking the vaccine was safe. According to him, they said, "*Isse khoon saaf hoga, bimari nahi hogi*"—This will clean your blood, protect you from the disease. The hospital gave Jitendra an injection which could either be the vaccine or a placebo. The Covaxin phase three trial is a double-blind and placebo-controlled, which means that neither the participants nor the investigators know who is getting a vaccine dose and who is getting a

placebo till the trial is unmasked at a later stage for analysis. According to the trial protocol uploaded on the Clinical Trial Registry of India, the Covaxin phase 3 trial aims to enroll 25,800 people randomly divided into the placebo and vaccine groups.

On 12 December, Jitendra woke up with a fever and headache. He went back to the hospital for a check up two days later. The doctors associated with the trial prescribed a few tests as well as medication, however the hospital did not pay for these tests and medication. Jitendra paid for a few tests himself. He got medicines from the Bhopal Memorial Hospital and Research Centre where, as a survivor of the gas leak of 1984, he is eligible for free treatment. The doctor at the trial site diagnosed him with jaundice, and prescribed more medicines and diagnostic tests. "I can't afford all of this, I am a daily wager and the sole earning member of the family," Jitendra said. He was borrowing money to support his parents, his nine-year-old son and five-year-old daughter because he had not been able to work for almost a month due to his illness. Jitendra has had fever for three weeks and he continues to feel weak. He is nauseous and unable to keep food down. "I am too weak to work now, we are living on borrowed money," he told me. Since late December, doctors from the trial site have stopped taking his calls.

According to the New Drugs and Clinical Trial Rules of 2019 (https://cdsco.gov.in/opencms/export/sites/CDSCO_WEB/Pdf-documents/NewDrugs_CTRules_2019.pdf), sponsors of a clinical trial must ensure medical management of trial volunteers who suffer an injury during the trial, unless the investigators prove that the injury is unrelated to the trial. The rules define medical management "as treatment and other necessary activities for providing the medical care to complement the treatment." Jitendra said he was prescribed tests and medication as soon as he went to the hospital to report his illness after the adverse event. He was not informed whether his symptoms were found to be related to the trial or not. I contacted the principal

investigator at People's Hospital, Dr Raghvendra Gumashta, who refused to comment on specific complaints of the participants. Gumashta is part of the teaching faculty for the community medicine department at the hospital. As the principal investigator, he is responsible for managing all aspects of the Covaxin trial at the Bhopal site "I can only say that we are doing everything as per instructions given by Bharat Biotech and you should speak to them regarding these allegations," he said. Bharat Biotech has not responded to emails asking whether they were aware of the adverse events faced by volunteers in Bhopal.

Deepak Bodh, a 19-year-old electrician, also said he participated in the Covaxin trial at the People's Hospital in Bhopal. He was also picked up in a van sent by the hospital for trial recruits in early December. He told me that he developed weakness and fatigue the day after he received the dose. These symptoms persisted for ten days during which period he was unable to work. "Even now I feel weak, I don't feel normal, so I have decided not to go for the next dose," he said. His 40-year-old father and 37-year-old mother also participated in the trial.

Hari Singh Gond, who is 50 years old, also a resident of Shankar Nagar and went to the trial in the hospital van, said he developed more serious symptoms after getting a first dose on 7 December. According to the prescription he shared with me, dated 10 December, he had symptoms including "loose motions, vomiting, body ache and headache," for which he was prescribed a few medicines by a doctor from the trial site. However, unlike Jitendra, Gond was not asked to pay for his medication.

Rachna Dhingra, a social activist who works with survivors of the Bhopal Gas leak in 1984, said that more than two hundred people were picked up from working class localities behind the Union Carbide plant, which was the source of the gas leak in 1984. In 2011, people in these localities who were survivors of the gas leak were subjected to an illegal clinical trial (https://www.ndtv.com/india-news/illegal-drug-trials-on-victims-of-bhopal-gas-tragedy-565178) during which 10 people died

(https://www.indiatoday.in/india/north/story/drug-trials-kill-10-bhopal-gas-victims-128363-2011-02-11#:~:text=Ten%20victims%20of%20the%201984,disaster%20case%20alleged%20on

Recruiters for the trial came in vans and announced that each person would get Rs 750 per trip to the hospital. “Paying 750 is a big incentive for these people,” Dhingra said. She also said that many volunteers did not have proper information before they enrolled in the trial. “Many of the volunteers who were picked up in these vans were not aware that this was a trial, others don’t have a copy of their consent form.”

Mukesh is 24 years old and sells biryani on the street. “Everyone was going, so my wife and mother also tagged along,” he said. “All they knew was they will receive Rs 750 and that they will get vaccinated against COVID-19.” He told me that he did not go to the hospital because he had to work.

Sangeeta Jaiswal, a 40-year-old woman from Shankar Nagar, went to the hospital with her 45-year-old husband, 22-year-old son and almost all the families from her lane. “We were told it is a vaccine that will protect us from corona. We were not informed about any trial,” she said.

According to the clinical trial rules, the “investigator must provide information about the study verbally as well as using a patient information sheet, in a language that is nontechnical and understandable by the study subject.” Trial investigators must also give a copy of the signed consent form to all volunteers. Jaiswal told me that neither was she able to read the form, nor did someone verbally explain what was written in the consent form to her. “They didn’t give us a copy of the form I signed. They gave us another sheet of paper along with some empty sheets of paper. They asked us to write on the sheets in case we develop a headache or weakness,” she said. The sheet of paper that Jaiswal refers to is a diary card, in which trial volunteers have to write down any symptoms they develop after they receive the trial drug or vaccine.

Gond, the 50-year-old volunteer who suffered an adverse event, also did not receive a signed copy of the consent form on his first visit to the hospital on 7 December. He was only given a copy of his consent form when he went for his second dose on 4 January. This consent form had the date of his January 2021 visit, but not of the December visit.

"The instances described are serious violations of the regulations on clinical trials, as well as violations of ethical principles of research," Sandhya Srinivasan, the consulting editor for the *Indian Journal of Medical Ethics*, said. "The participant's voluntary and informed consent is central to ethical research. Researchers must not exploit potential participants' vulnerabilities that might limit their ability to give voluntary consent. People who are economically disadvantaged, who are seeking healthcare, who cannot read or who have limited education– these are among the groups who should not be recruited without good reason."

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