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UK Will Infect Healthy Young People With COVID in World's First Human Challenge Trial

Proponents say first human COVID trials will yield valuable information, but critics argue that with no cure for the potentially deadly virus, the trials are unethical.

By Megan Redshaw

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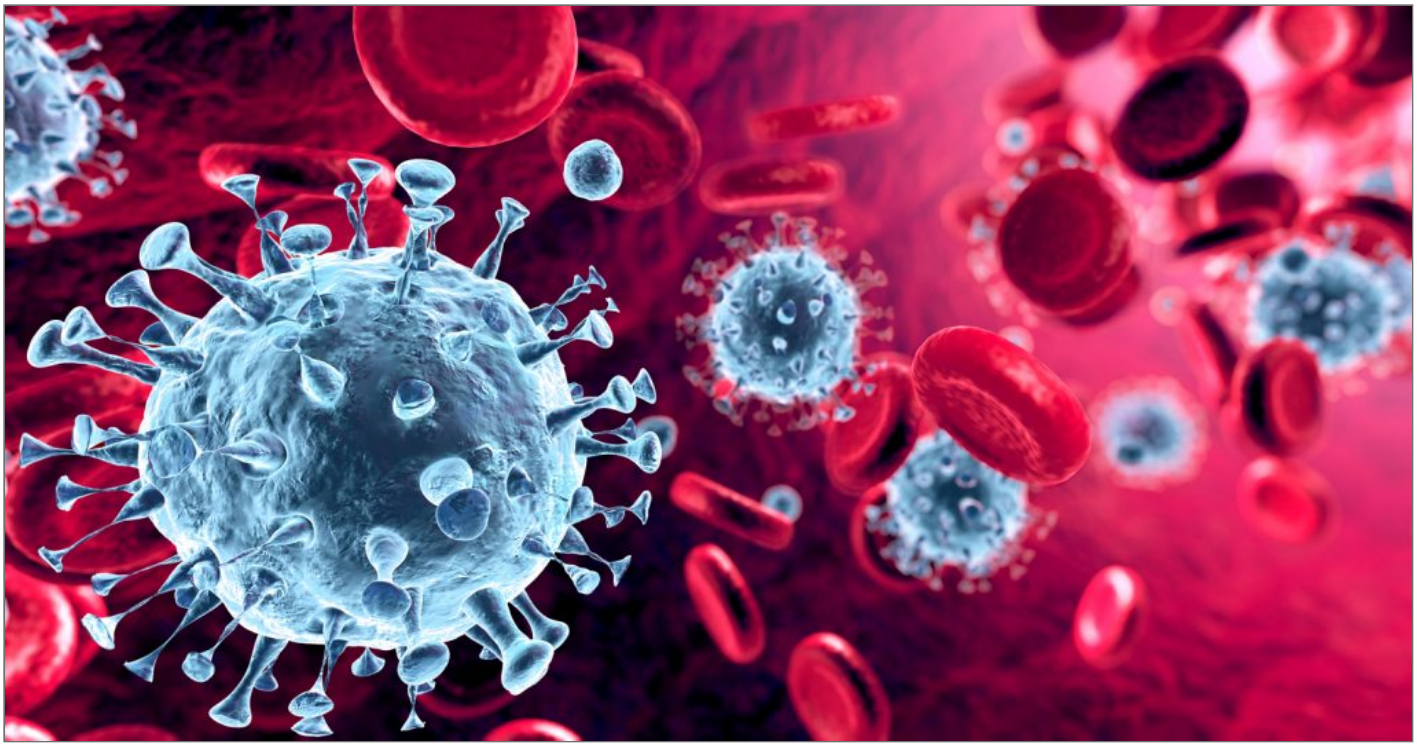

The UK announced Wednesday that it will be the first country to run human challenge trials on COVID-19, a type of study that requires deliberately infecting healthy people with the potentially deadly virus.

The controversial study — the first of its kind on COVID — is geared toward understanding the virus, testing the effectiveness of current vaccines and accelerating development of newer vaccines, according to a UK government press release.

Proponents of the strategy say it's about saving lives by speeding up development of vaccines and understanding the virus. According to The New York Times, scientists and bioethicists say the risk of coronavirus "seriously sickening or killing young, healthy volunteers — the sort of people who would be infected — is low enough as to be outweighed by the possibility of saving tens of thousands of lives."

But critics of human challenge trials suggest that infecting healthy people with a potentially deadly virus, for which there is no cure, is unethical.

In an op-ed published in November, by the Proceedings of the National Academy of Sciences (PNAS), five medical experts said moving forward with human challenge studies on COVID-19 is unethical.

They wrote:

> "Whereas proponents of these studies suggest that such studies will accelerate the time to approve vaccines, the facts fail to support these claims. HCS to address SARS-CoV-2 face unacceptable ethics challenges, and, further, undertaking them would do a disservice to the public by undermining already strained confidence in the vaccine development process."

So far, thousands of volunteers have signed up for the UK's COVID human challenge trials through 1 Day Sooner, a U.S. advocacy group that "lobbies for challenge trials to accelerate vaccine development."

Here's how the study will work

As CBS News reported, 90 volunteers ages 18 – 30 will participate in the initial study, which is called a characterization study, where scientists will administer tiny droplets of the SARS-CoV-2 virus into the nostrils of unvaccinated participants to determine the smallest amount needed to cause infection.

According to WIRED, researchers will gradually increase the dose with each group of volunteers to determine the smallest amount that triggers infection in the majority of people. This will be assessed by measuring the virus that comes out of participants' noses, known as "viral shedding."

Participants will then quarantine in a hospital for 14 days and be monitored daily by a medical team to determine how the immune system responds and whether certain factors influence transmission of the virus.

During this first phase of research, scientists will use the version of the virus circulating in the UK since the beginning of the pandemic.

Once researchers have determined the smallest amount of virus needed to trigger infection, subsequent studies will be done using approved vaccines. Scientists hope to vaccinate small groups of people and then introduce them to COVID, based on the "smallest amount" required to infect them, as determined during the initial trial. They will then monitor the subjects in hope of determining which vaccines are most effective.

It is unclear how U.S. or European regulators will evaluate the results or whether these studies will actually accelerate the vaccine approval process, according to the Times.

With no cure for COVID, are human trials ethical?

The idea of human challenge trials has been met with lukewarm reception by some vaccine makers, including Johnson & Johnson and Moderna.

Dr. Paul Stoffels, chief scientific officer at Johnson & Johnson, told the Times that he "would consider challenge trials only if a treatment became available" and that "traditional phase 3 trials would provide more safety information."

Dr. Tal Zaks, chief medical officer of Moderna, is already working on phase 3 trials and said the issue would likely be more relevant to vaccines being developed behind the Moderna vaccine. "If a model were available, we would look at it, but we would hate to put people in harm's way," he said in an interview.

But the manufacturer of the controversial AstraZeneca-Oxford vaccine said it plans to do a human challenge trial by the end of the year to test vaccine efficacy. Dr. Adrian Hill, director of the Jenner Institute at University of Oxford, told the Times: "The trials would be acceptable, even without treatment" and "these studies are a good way to compare vaccines."

Although human challenge trials have been done in the past with malaria, cholera, typhoid and influenza vaccines, COVID-19 is different because there is no rescue therapy to treat those who become infected and the disease is not self-limiting, the authors of the PNAS op-ed said.

Reporting this week on the UK study, TIME magazine pointed out that when volunteers developed cholera during human challenge trials for the recently approved cholera vaccine, serious cases were treated with antibiotics, a proven treatment. With no known cure for COVID-19, British scientists are in uncharted ethical territory.

Dr. Kirsten Lyke, professor of medicine at University of Maryland told TIME:

> "There are treatments for them [malaria, cholera and influenza]. So after getting exposed to the disease in the trial, if volunteers got very sick, they could quickly be treated."

Some critics of COVID human challenge trials argue that even if the studies accelerate vaccine development, the U.S. Food and Drug Administration, if following its vaccine approval standards, will not consider data from the studies in its licensing decisions. Late-phase clinical trials enroll thousands of participants and adequately represent the elderly and individuals with comorbidities, which are excluded from human challenge trials.

Using a human challenge trial to determine deaths averted hinges on the premise of high-risk groups receiving an effective vaccine sooner. However, guidelines for the UK study recommend enrolling only young, healthy adults. This reduces the risks with these types of studies but jeopardizes the results. Further vaccine trials using standard methodology would still be needed to ensure safety and efficacy for those who do not fit the inclusion criteria of participants in the trial, critics said.

In the past, human trials haven't turned out well

Although human challenge trials conducted in the past have yielded important information for the scientific community, these controversial human experiments have raised serious ethical questions about human challenge trials for COVID vaccines. In question is whether it's right to risk the health of a few for the benefit of the many.

For example, Smithsonian Magazine reported how pathologist Walter Reed, in 1898, wanted to figure out how yellow fever spread and how to stop it. He first allowed mosquitoes to bite yellow fever patients and then exposed the infected mosquitoes to healthy volunteers.

One of the scientists running the study died when he was accidentally bitten. Although results confirmed that insects caused yellow fever and the first-ever virus was isolated, subsequent studies resulted in numerous deaths as Reed unknowingly infected participants with a more virulent strain. It was later discovered that participants were vulnerable and not fully informed of the risks.

The controversial Tuskegee Syphilis Study, frequently referred to as the Tuskegee Experiment, was conducted by the U.S. Public Health Service, beginning in 1932. The study recruited 600 Black American men. The goal was to observe the natural history of untreated syphilis in the Black population, but subjects were told they were receiving treatment for "bad blood." Only half of the participants received any type of treatment, which included doses of toxic arsenic and mercury. The rest received no treatment at all.

Instead of observing the natural progression of syphilis, the Tuskegee researchers lied to participants and prevented them from seeking life-saving care when a safe and reliable cure became available. Only two-thirds of the men actually had syphilis. When the study was forced to end 40 years later, only 74% of participants with syphilis survived.

Although the Tuskegee Experiment involved individuals who were already ill, other experiments involved exposing healthy people to deadly diseases. From 1955 – 1970, pediatric physician Saul Krugman conducted a monstrous experiment on mentally disabled children at Willowbrook State School to develop hepatitis vaccines.

These experiments involved infecting more than 50 healthy children with hepatitis to determine how long it would take children to show symptoms and how their immune systems would respond.

Krugman justified the risks because the strain wasn't severe — children would likely get infected anyway and the experiment was to benefit others. Although the results differentiated the hepatitis A and B strains and sped up the development of the hepatitis B vaccine, results were replicated during that same time period by analyzing blood samples of already infected adults.

In 1966, anesthesiologist Henry Beecher published a landmark essay with 22 examples of unethical research on humans despite the creation of international human experimentation guidelines — the Declaration of Helsinki in 1964 and the Nuremberg Code.

The Nuremberg Code is the benchmark of medical and research ethics that serves as a blueprint for human rights in medical research. Enacted in 1947 in Nuremberg, Germany, the code was developed in response to the horrors of human experimentation done by Nazi physicians in concentration camps.

The Nuremberg Code details a 10-point set of rules for conducting human experiments. It specifies that experiments should be designed and based on the results of animal experimentation, that they should avoid all necessary physical and mental suffering and injury, and that "no experiment should be conducted where there is [...] reason to believe that death or disabling injury will occur; except, perhaps, in those experiments where the experimental physicians also serve as subjects."

The views and opinions expressed in this article are those of the authors and do not necessarily reflect the views of Children's Health Defense.

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Megan Redshaw

Megan Redshaw is a freelance reporter for The Defender. She has a background in political science, a law degree and extensive training in natural health.

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