



The BMJ

Cite this as: *BMJ* 2020;371:m4101<http://dx.doi.org/10.1136/bmj.m4101>

Published: 22 October 2020

Covid-19: Human challenge studies will see people purposefully infected with virus

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Human challenge studies of covid-19, which involve volunteers being deliberately infected with the virus under controlled conditions, could start in January, UK researchers have said.

The project, which would be a world first, is a collaboration between Imperial College London, hVIVO (part of the drug company Open Orphan), and the Royal Free London NHS Foundation Trust. It has been supported by the government through a £33.6m (\$37m; \$44m) investment.

In the first stage the researchers will work to determine the smallest amount of virus needed to cause infection and elicit an immune response. To do this they will slowly increase the viral dose to which small groups of volunteers are exposed.

In the second stage vaccine candidates that have been shown to be safe in initial trials will be given to a small number of healthy volunteers, who will then be exposed to the virus. The team will then monitor the participants to see how the vaccine works and to identify any side effects.

The researchers will recruit healthy volunteers aged 18 to 30 who have no previous history or symptoms of covid-19, no underlying health conditions, and no known adverse risk factors for covid-19, such as heart disease, diabetes, or obesity. Any participants who develop covid-19 will be treated with remdesivir as soon as the infection is confirmed.

The vaccine candidates that will be tested in the second stage have not yet been selected.

Claire Waddington, clinical lecturer in infectious diseases at the University of Cambridge, said, “These models have been successfully used to accelerate the development of vaccines against difficult pathogens such as *Salmonella typhi* (the cause of typhoid fever), as well as providing us with detailed understanding of the different diseases. They can also be used to develop and improve our understanding of diagnostic tests and treatments.”

The studies still need to be approved by the UK Medicines and Healthcare Regulatory Agency and an ethics committee.

Lead researcher Chris Chiu, from the department of infectious disease at Imperial College London, said, “Our number one priority is the safety of the volunteers. My team has been safely running human challenge studies with other respiratory viruses for over 10 years. No study is completely risk free, but the Human Challenge Programme partners will be working hard to ensure we make the risks as low as we possibly can.”

Co-investigator on the study Peter Openshaw, director of the MRC funded Human Challenge Consortium at Imperial College London, said, “Deliberately infecting volunteers with a known human pathogen is never undertaken lightly. However, such studies are enormously informative about a disease, even one so well studied as covid-19.

“It is really vital that we move as fast as possible towards getting effective vaccines and other treatments for covid-19, and challenge studies have the potential to accelerate and de-risk the development of novel drugs and vaccines. These studies form a part of the global effort and play to a unique strength that we have at Imperial and in the UK.”