

World's first coronavirus Human Challenge study receives ethics approval in the UK

- First Covid-19 human challenge study will begin within a month, after receiving ethics approval in the same week the UK hits target of offering first dose to 15 million people
- Researchers call on healthy young people to volunteer for the study, which will play a key role in developing effective Covid-19 vaccines and treatments
- Up to 90 volunteers aged 18 – 30 years will be exposed to Covid-19 in a safe and controlled environment to increase understanding of how the virus affects people

Backed by a £33.6 million UK government investment, the first-of-its-kind study for this virus will involve establishing the smallest amount of virus needed to cause infection, which will give doctors greater understanding of Covid-19 and help support the pandemic response by aiding vaccine and treatment development.

Due to begin in the next few weeks, it will involve up to 90 carefully selected, healthy adult volunteers being exposed to the virus in a safe and controlled environment.

The safety of volunteers is paramount, which means this virus characterisation study will initially use the version of the virus that has been circulating in the UK since March 2020 and has been shown to be of low risk in young healthy adults. Medics and scientists will closely monitor the effect of the virus on volunteers and will be on hand to look after them 24 hours a day.

The researchers are also working very closely with the Royal Free Hospital and the North Central London (NCL) Adult Critical Care Network to ensure the study will not impact on the NHS' ability to care for patients during the pandemic. The study will not begin without their go-ahead.

Once this initial study has taken place, vaccine candidates, which have proven to be safe in clinical trials, could be given to small numbers of volunteers who are then exposed to the Covid-19 virus, helping to identify the most effective vaccines and accelerate their development.

Researchers are encouraging people aged between 18 and 30 years old, who are at the lowest risk of complications resulting from coronavirus, to volunteer for this vital study. Volunteers will be compensated for the time they spend in the study.

Business Secretary Kwasi Kwarteng said:

Researchers and scientists around the world have made incredible progress in understanding Covid-19 and developing critical vaccines to protect people.

While there has been very positive progress in vaccine development, we want to find the best and most effective vaccines for use over the longer term. These human challenge studies will take place here in the UK and will help accelerate scientists' knowledge of how coronavirus affects people and could eventually further the rapid development of vaccines.

Over many decades, human challenge studies have been performed safely and have played important roles in accelerating the development of treatments for diseases including malaria, typhoid, cholera, norovirus and flu. The trials have also helped researchers establish which possible vaccine is most likely to succeed in phase 3 clinical trials that would follow, usually involving thousands of volunteers.

This initial study will also help doctors understand how the immune system reacts to coronavirus and identify factors that influence how the virus is transmitted, including how a person who is infected with Covid-19 virus transmits infectious virus particles into the environment.

The Human Challenge study is being delivered by a partnership between the government's Vaccines Taskforce, Imperial College London, the Royal Free London NHS Foundation Trust and the industry-leading clinical company hVIVO, which has pioneered viral human challenge models.

The Royal Free Hospital's specialist and secure clinical research facilities in London are specifically designed to contain the virus. Highly trained medics and scientists will be on hand to carefully examine how the virus behaves in the body and to ensure the safety of volunteers.

The virus being used in the characterisation study has been produced by a team at Great Ormond Street Hospital for Children NHS Foundation Trust in London, in collaboration with hVIVO with support from virologists at Imperial College London.

Interim Chair of the Vaccines Taskforce Clive Dix said:

We have secured a number of safe and effective vaccines for the UK, but it is essential that we continue to develop new vaccines and treatments for Covid-19. We expect these studies to offer unique insights into how the virus works and help us understand which promising vaccines offer the best chance of preventing the infection.

Chief Investigator Dr Chris Chiu, from Imperial College London, said:

We are asking for volunteers aged between 18 and 30 to join this research endeavour and help us to understand how the virus infects people and how it passes so successfully between us. Our eventual aim is to establish which vaccines and treatments work best in beating this disease, but we need volunteers to support us in this work.

Chief Scientific Officer at hVIVO, Dr Andrew Catchpole said:

Ethical review of the research plan is a crucial part of conducting clinical studies and approval from the Ethics Committee represents a very important milestone in the development of the Covid-19 challenge model. COVID-19 Human Challenge studies have the potential to play an important role in providing data and information that will help continue to develop vaccines to control the pandemic.

This study is a key enabling study to establish the Covid-19 challenge model and determine the lowest possible dose of virus required. Data from this study will immediately facilitate the challenge model to be used for vaccine efficacy testing as well as to answer a wide range of fundamental scientific questions that are not feasible with traditional field trials, such as exactly what type of immunological response is required to confer protection from re-infection.

People can express an interest in taking part in this research at <https://ukcovidchallenge.com/>