

Coronavirus treatment

UK to test vaccines on volunteers deliberately infected with Covid-19

'Human challenge trials' intended to accelerate vaccine development programmes



A clinic run by hVivo has been earmarked for the initial challenge trials © Chris Dawes/hVIVO

Clive Cookson in London 3 HOURS AGO

London is to host the world's first Covid-19 human challenge trials — in which healthy volunteers are deliberately infected with coronavirus to assess the effectiveness of experimental vaccines.

The UK government-funded studies are expected to begin in January at a secure quarantine facility in east London, according to several people involved in the project, which will be announced next week.

The researchers, who did not want to comment publicly ahead of the launch, said the trials would play a vital role in narrowing the large field of promising [Covid-19 vaccines](#) likely to move into clinical testing early next year.

Volunteers will be inoculated with a vaccine and a month or so later receive a “challenge” dose of Sars-Cov-2, the virus that causes Covid-19, under controlled conditions.

About 2,000 potential volunteers have signed up for challenge studies in the UK through the US-based advocacy group 1Day Sooner, which campaigns for Covid-19 infection trials and has enlisted 37,000 people worldwide. Traditional clinical trials need tens of thousands of participants and researchers would struggle to attract enough for multiple vaccine studies.

Challenge trials have a long history dating back to 1796, when the vaccine pioneer Edward Jenner inoculated eight-year-old James Phipps with live cowpox virus. More recently, they have been instrumental in developing vaccines and treatments for typhoid, cholera and malaria and in understanding how the immune system responds to flu and other viruses.

1Day Sooner is launching a UK campaign this week with a petition to parliament asking for public funding of a biocontainment facility with enough capacity to quarantine 100 to 200 participants.

The project's academic leader is Imperial College London, and it will be run by hVivo, a spinout from Queen Mary University of London that was bought earlier this year by Open Orphan, a Dublin-based pharmaceutical research organisation.

A final decision about the site of the initial challenge trials has not been made. It may be at hVivo's 24-bed quarantine clinic in Whitechapel, London, or at another larger location nearby.

Dominic Wilkinson, professor of medical ethics at Oxford university, is one of several prominent ethicists in the UK who have already signed the 1Day Sooner petition.

“When we are facing an unprecedented global threat from Covid, it is an ethical imperative to carry out well controlled challenge studies to help develop a vaccine and then to identify the best vaccines,” said Prof Wilkinson. “The ones emerging first from clinical trials are unlikely to be the best.”

Any Covid-19 challenge trial will need to be approved by the UK Medicines and Healthcare products Regulatory Agency and an independent research ethics committee.

“Human challenge trials can be helpful for the development of vaccines and can provide early evidence of clinical efficacy, particularly when there are low rates of infection of the virus in the population,” said the MHRA.

“The safety of trial participants is our top priority and any proposal from a developer to include a human infection challenge as part of a clinical trial for development of a vaccine would be considered on a benefit-risk basis, with risks monitored for and minimised in the proposed trial design.”

The petition organiser of [1Day Sooner](#) in the UK is 18-year-old Alastair Fraser-Urquhart who is devoting his time to the campaign before going to University College London to study cancer biology next year.



Alastair Fraser-Urquhart is the lead organiser of 1Day Sooner in the UK

“By exposing just a few hundred carefully selected young, healthy people to coronavirus — a virus which for this group is far less deadly than routine procedures such as a live kidney donation — we can test a huge range of vaccines very quickly,” said Mr Fraser-Urquhart.

One crucial aspect of challenge trials is to select and purify an appropriate strain of the virus that is genetically representative of Sars-Cov-2 currently circulating in the population, and choose doses that will infect volunteers without overloading their immune system.

It is also essential to have a “rescue remedy” on hand to prevent serious illness in participants. The London trial will initially use remdesivir, the only antiviral drug so far proven to work against Covid-19.

Volunteers who take part in hVivo’s influenza challenge studies receive up to £3,750 compensation. The payment for Covid-19 trials is likely to be somewhat higher because the isolation will last longer — potentially as long as a month.

The hVivo facility could be divided into three zones of eight beds each, to test three different vaccines at the same time. There is likely to be intense demand for its services and larger facilities may be opened later.

In the US the National Institutes of Health has awarded Colorado State University a contract worth at least \$3.6m to support the manufacturing of two viral strains that could be used for human challenge studies. It is currently preparing the manufacturing process for one of the strains. NIH is also investigating the technical and ethical requirements for challenge trials.

But Nadine Rouphael, a leading vaccine researcher at Emory University in Atlanta and one of several scientists who are keen to carry out challenge studies in the US, said: “There is no urgency at NIH. The UK is well ahead — and that’s great.”

This story has been amended to make clear that the initial site for the challenge trials has not been decided.

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