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## Sixty seconds on . . . human challenge trials

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### Not another reality TV programme?

Thankfully, no. I'm referring to human challenge trials in which healthy volunteers are exposed to a pathogen to learn more about the disease it causes and to test vaccines quickly.<sup>1</sup>

### So, this is about covid-19?

Isn't everything? Yes, you're right, I'm specifically talking about the world's first covid-19 human challenge trial that the UK government announced will begin within a month.<sup>2</sup>

### How will it work?

Up to 90 healthy volunteers aged 18 to 30 will be exposed to covid-19 in a "safe and controlled environment" at the Royal Free Hospital in London.

### How will they be infected?

Don't worry, this isn't a covert excuse for a party. The virus being used has been produced at Great Ormond Street Hospital, London, in collaboration with the company hVIVO.

### Will the volunteers become unwell?

Stephen Griffin, associate professor in the School of Medicine, University of Leeds, says the volunteers will be given remdesivir as soon as infection is confirmed. He says it's unlikely that any of the participants will become very sick, but there is still a small risk because existing treatments—such as dexamethasone and tocilizumab—don't work for everyone. He also noted that even mild infection could cause long term morbidity, even following a relatively mild infection.

### It had better be worth it

The aim is to 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 transmits infectious virus particles into the environment.

### So this isn't about vaccines?

Not yet. But, after this first stage of the trial, vaccine candidates that have proven to be safe in clinical trials could be given to small numbers of volunteers to identify the most effective ones and accelerate their development.

### Is this even ethical?

The study was approved by a specially appointed independent research ethics committee. Before this, authors from 1Day Sooner—a non-profit organisation that advocates on behalf of volunteers for a potential covid-19 human challenge trial—debated the matter in *The BMJ* and cited the principle of "risk parity."<sup>1</sup> "If we allow some people to take certain risks to help save lives then we should allow other people to take

similar, voluntary risks when there are comparable benefits," they said.

### Has this been done before?

Yes. Lawrence Young, virologist at the University of Warwick, says human challenge trials have a long history. "They have been used to study infections, treatments, and vaccines for many different organisms ranging from common cold viruses to malaria."

### That's hopeful?

Fingers crossed. Charlie Weller, head of vaccines at the Wellcome Trust, says this trial could speed up vaccine development and provide key insights into new treatments. "Together, effective treatments, vaccines, and testing will help communities around the world to protect themselves and bring this pandemic to an end," he said.

1 McPartlin SO, Morrison J, Rohrig A, Weijer C. Covid-19 vaccines: Should we allow human challenge studies to infect healthy volunteers with SARS-CoV-2? *BMJ* 2020;371:m4258. doi: 10.1136/bmj.m4258 pmid: 33168564

2 Department for Business, Energy, and Industrial Strategy. World's first coronavirus human challenge study receives ethics approval in the UK. 17 February 2021. [www.gov.uk/government/news/worlds-first-coronavirus-human-challenge-study-receives-ethics-approval-in-the-uk](http://www.gov.uk/government/news/worlds-first-coronavirus-human-challenge-study-receives-ethics-approval-in-the-uk).

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