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Covid-19: Oxford researchers halt vaccine trial while adverse reaction is investigated

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One of the leading covid-19 vaccine candidate trials has been voluntarily paused as part of a standard review process triggered by a "single event of an unexplained illness that occurred in the UK phase III trial."

The candidate vaccine, developed at the University of Oxford in partnership with AstraZeneca, is being tested in multiple countries around the world, including the UK, Brazil, and South Africa, to see whether it is effective against SARS-CoV-2, the virus that causes covid-19.[1]

However, the phase III trial has now been halted "to allow an independent committee to review the safety data," the drug company said on 9 September. "This is a routine action which has to happen whenever there is a potentially unexplained illness in one of the trials, while it is investigated, ensuring we maintain the integrity of the trials. AstraZeneca is working to expedite the review of the single event to minimise any potential impact on the trial timeline," the statement said.

AstraZeneca's chief executive officer, Pascal Soriot, said, "We will be guided by this committee as to when the trials could restart, so that we can continue our work at the earliest opportunity to provide this vaccine broadly, equitably, and at no profit during this pandemic."

Speaking at a Wellcome Trust covid-19 vaccine briefing on 9 September, Jeremy Farrar, the trust's director, said, "Pausing a vaccine trial is very common. It is very unusual to go through a vaccine trial and not pause. In many ways it shows that the oversight of the trial is working well, and it is critical that that information is shared transparently and openly around the world . . .

"As far as I'm aware we don't know whether this was in the control or vaccine arm. When you're studying tens of thousands of individuals and you're following them for weeks and months afterwards, I'm afraid to say health issues do arise. When you're following that many people there will be events, some of which would have happened anyway and some of which may or may not be linked to the trial itself."

The ChAdOx1 nCoV-19 vaccine uses an adenovirus vaccine vector and the genetic sequence for the SARS-CoV-2 spike protein. After the vaccine has been administered the spike protein is produced, which primes the immune system to recognise and attack the virus if the vaccinated person is infected in the future.

1 Mahase E. Covid-19: Oxford team begins vaccine trials in Brazil and South Africa to determine efficacy. *BMJ* 2020;369:m2612. doi: 10.1136/bmj.m2612 pmid: 32601063