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## Covid-19: AstraZeneca vaccine prevents 79% of symptomatic disease and 100% of severe disease, US study finds

Shaun Griffin

Interim analysis of a phase III trial has found that the vaccine produced by Oxford University and AstraZeneca was 79% effective at preventing symptomatic covid-19 and 100% effective at preventing severe disease and admission to hospital. The results, announced in an AstraZeneca press release, have yet to be formally peer reviewed.

Among the 32 449 participants, randomised 2:1 to vaccine and placebo groups, in the trial, which was carried out in the US, Chile, and Peru, there were 141 symptomatic cases of covid-19, the announcement said. The two doses of the vaccine were administered four weeks apart.

The finding that the vaccine had 80% efficacy among participants aged over 65 years (a fifth of the total in the trial) provides reassurance after Germany and some other European countries had failed to approve the vaccine for use in this age group, citing a lack of data.<sup>1</sup> About 60% of the participants aged over 65 years had comorbidities associated with an elevated risk of severe covid-19 disease, such as diabetes, severe obesity, or cardiac disease.

A review by the study's independent data safety monitoring board and an independent neurologist found no increased risk of thrombosis or events characterised by thrombosis among the 21 583 participants who received at least one dose of vaccine.

There were also no events of cerebral venous sinus thrombosis, a condition that recently resulted in a pause in use of the vaccine in some countries.<sup>2</sup> Many countries have now resumed their vaccination programme with the Oxford-AstraZeneca vaccine after the European Medicines Agency concluded that its use was not linked to an increased risk of blood clots, although some countries, including France, Denmark, Norway, Sweden, and Finland, have not lifted all their restrictions on its use.

Vaccine efficacy was consistent across ethnic groups, the trial's interim analysis showed. Around 79% of participants were white, 22% Hispanic, 8% black or African American, 4% native American, and 4% Asian.

AstraZeneca said it will submit the results for publication in a peer reviewed journal. After further analysis in the coming weeks it will also submit the data to the US Food and Drug Administration for emergency use authorisation.

Sarah Gilbert, professor of vaccinology at Oxford University, who led development of the vaccine there, said she couldn't see any reason why the FDA would not approve the vaccine for use in the US after scrutinising the data.

Speaking about the study, Stephen Evans, professor of pharmacoepidemiology at the London School of Hygiene and Tropical Medicine, said, "These results are not surprising given what we know now. The US regulatory authorities are reluctant, even in a pandemic, to rely totally on data obtained outside the US, so this trial was done to provide convincing evidence of efficacy and safety in a sufficiently large number of US patients.

"The benefits of these results will mainly be for the rest of the world, where confidence in the AstraZeneca vaccine has been eroded, largely by political and media comment. Once that happens, reporting of adverse effects becomes very biased, and confidence can spiral downwards. The rest of the world that will rely on this low cost vaccine may be able to proceed with vaccinating their populations."

- 1 Boytchev H. Covid-19: Germany struggles with slow uptake of Oxford AstraZeneca vaccine. *BMJ* 2021;372:n619. doi: 10.1136/bmj.n619 pmid: 33658177
- 2 Mahase E. Covid-19: AstraZeneca vaccine is not linked to increased risk of blood clots, finds European Medicine Agency. *BMJ* 2021;372:n774. doi: 10.1136/bmj.n774 pmid: 33741638

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