News

Covid-19: Study reports no significant increase in deaths after vaccination but raises questions over AstraZeneca's vaccine

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Researchers have found no significant increase in mortality in young people in the 12 weeks after a covid-19 vaccination, when compared with the longer term risk, but reported an increase in cardiac death in women after a first dose of non-mRNA vaccines.

The study by the Office for National Statistics used a combination of ONS registered deaths (3807), hospital episode statistics (1420), and vaccine records for England, to assess the effect of covid vaccination and positive SARS-CoV-2 test results on the risk of cardiac and all cause mortality in people aged 12 to 29.[1,2]

Through a self-controlled case series design, where each participant acted as their own control, they compared the risk of death in the 12 weeks after vaccination to a period after 12 weeks.

The UK rolled out Pfizer and BioNTech's mRNA vaccine in December 2020 and Moderna's in April 2021. It also used the Oxford-AstraZeneca vaccine, rolled out in January 2021, but then withdrew it for people aged under 30 on 7 April 2021 because of concerns over potential blood clot links.[3] Until 8 June 2021 vaccination in this young age group was limited to healthcare workers and people who were clinically extremely vulnerable.

The study, published in *Nature Communications*, found "no significant increase" in cardiac or all cause mortality in the 12 weeks after vaccination when compared with the period more than 12 weeks after any dose. But the researchers did see an increase in cardiac death in women after a first dose of non-mRNA vaccines (such as the Oxford-AstraZeneca), with the risk being 3.5 times higher in the 12 weeks after vaccination, when compared with the longer term risk.

The researchers assessed that 11 of the 15 cardiac deaths in young women that occurred within 12 weeks of a first dose of a non-mRNA vaccine were likely to be linked to the vaccine. This equated to six cardiac related deaths per 100 000 females vaccinated with at least a first dose of a non-mRNA vaccine.

The findings came as 75 claimants launched legal action against AstraZeneca in the UK over a rare side effect of its covid vaccine. Those taking legal action have diagnoses of vaccine induced thrombotic thrombocytopenia.[4]

A positive SARS-CoV-2 test was also associated with increased cardiac and all cause mortality, with the risk found to be higher in people who were unvaccinated.

Vahé Nafilyan, study author and ONS senior statistician, said, "Vaccination with the main non-mRNA vaccine used in the UK was stopped for young people following safety concerns in April 2021, and most of the young people who received it would have been prioritised due to clinical vulnerability or being healthcare workers. Therefore, these results cannot be generalised to the population as a whole.

"While vaccination carries some risks, these need to be assessed in light of its benefits. Our analysis shows that the risk of death is greatly increased following a positive test for covid-19 even in young people, and many studies show that vaccines are highly effective at preventing hospitalisation or death following covid-19 infection."

The authors noted limitations to their study, including that there were delays in death registration over coroner referrals, meaning that not all deaths that occurred in the period studied would have been registered.

Additionally, the study design meant that the researchers could not compare people who were vaccinated with those who were unvaccinated at the time of a positive SARS-CoV-2 test. "These groups can be expected to differ in important ways such as comorbidity and strain of SARS-CoV-2," they wrote.

"More questions to answer"

Commenting on the study, Stephen Evans, emeritus professor of pharmacoepidemiology at the London School of Hygiene and Tropical Medicine, said the differences noted between men and women were not yet understood. But he said, "This study does not estimate vaccine effectiveness, and it is difficult to assess the exact balance of benefit and harm in this age group for the time when omicron was prevalent, but it is clear that infection with this virus can, rarely, lead to death in this age group, and death following vaccination is even rarer."

Adam Finn, professor of paediatrics at the University of Bristol, said the study generated "as many questions as answers."

Finn, a member of the Joint Committee on Vaccination and Immunisation (JCVI) and the World Health Organization's covid-19 vaccine advisory group, said, "The next and most pressing issue that needs to be addressed is to gather more detailed information on what the nature of the reported cardiac events actually was, as this would help us begin to understand what is really being seen in these figures and might help guide future policy and vaccine design."

Finn was also chief investigator on the UK clinical trials programmes for the Valneva and Sanofi-GSK vaccines and investigator on several other covid vaccine trials and studies, including Oxford-AstraZeneca and Pfizer-BioNTech vaccines. He is currently involved in the planning of trials of vaccines being developed by Moderna.

The BMJ tried to contact AstraZeneca UK several times but received no response.

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Should covid-19 vaccines and drugs be “not for profit”?

- ○ Yes
- ○ No

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