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Covid-19: Pfizer reports 100% vaccine efficacy in children aged 12 to 15

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The Pfizer-BioNTech covid-19 vaccine has shown 100% efficacy against SARS-CoV-2 in 12 to 15 year olds in the preliminary results of a phase III trial.

Pfizer announced the results in a press release, although full details have yet to be published. It said that it would now submit the data to the US Food and Drug Administration and the European Medicines Agency as it requests expanded marketing authorisation.

“We plan to submit these data to the FDA as a proposed amendment to our emergency use authorisation in the coming weeks and to other regulators around the world, with the hope of starting to vaccinate this age group before the start of the next school year,” said Albert Bourla, Pfizer’s chief executive officer.

The phase III trial included 2260 children in the US. A total of 18 cases of covid-19 were observed in the placebo group (n=1129), while none was reported in the vaccinated group (n=1131). The vaccine also elicited robust antibody responses and was well tolerated, with side effects consistent with those observed in participants aged 16 to 25.

Pfizer will now submit the data for peer review and publication, and trial participants in the trial will be monitored for two years to determine long term protection and safety.

Population immunity

Stephen Griffin, associate professor at the University of Leeds School of Medicine, said, “In short, this is fantastic news. Demonstrating efficacy and safety in younger patients is an important step forwards in terms of enabling eventual population immunity against SARS-CoV-2.

“It will enable a long term programme of school based vaccination to be implemented following the initial rollout, ensuring that our population is well protected from the virus in the future. It will also be important to alleviate the concerns of parents and teachers alike regarding the spread of infection within schools, and [it is] far and away more preferable than mass testing and mitigation measures in the longer term.”

The Pfizer vaccine has already been rolled out to some children in Israel, where the health ministry recommended vaccinating some older children with underlying conditions that make them vulnerable to the effects of the virus, such as cystic fibrosis.¹

Meanwhile, the director of the US National Institute of Allergy and Infectious Diseases, Anthony Fauci, has said that high school students throughout the US should be able to get a vaccine in the autumn.

A vaccine trial in children aged 6 months to 11 years has also been launched, and the first healthy children received a vaccine dose last week. The study will evaluate the safety, tolerability, and immunogenicity of the vaccine (two doses, 21 days apart) in three age groups: 5 to 11 years, 2 to 5 years, and 6 months to 2 years.

1 Mahase E. Covid vaccine could be rolled out to children by autumn. *BMJ* 2021;372:n723. doi: 10.1136/bmj.n723 pmid: 33727232

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