

Early results show Pfizer-BioNTech COVID vaccine safe, highly effective in adolescents

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Credit: Pfizer

Interim study data released today show that the Pfizer-BioNTech coronavirus vaccine is 100% effective in preventing infections in 12-15 year olds. The vaccine is currently approved for emergency use in people

16 and older.

"This data is very encouraging and appears to mirror the findings in adults, which show this is a safe and very efficacious vaccine" said Ann Falsey, M.D., professor of Medicine, Infectious Diseases, and co-director of the University of Rochester Medical Center (URMC) Vaccine and Treatment Evaluation Unit. "New vaccines are typically evaluated in descending [age groups](#), so this study represents a critical first step to expand eventual use into children and infants."

Falsey and Edward Walsh, M.D., have been involved in the Pfizer-BioNTech vaccine [clinical trials](#) in adults since May 2020 when volunteers in Rochester were among the first in the nation received the then-experimental vaccine. URMC was not involved in the adolescent vaccine study.

The results reported today came from a clinical trial that included 2,260 adolescents 12 to 15 years of age. During the study, 18 cases of COVID-19 were observed in the [placebo group](#), versus none in the vaccinated group. The study also showed the vaccine elicited a strong immune response and was safe and well tolerated, with side effects that were consistent with those reported in persons 16 to 25 years of age. The companies said they would soon submit the data to the Food and Drug Administration as an amendment to the agency's prior Emergency Use Authorization for the vaccine.

"These results are a great start in ensuring the public has access to a safe and effective pediatric vaccine," said Mary Caserta, M.D. a professor in the URMC Department of Pediatrics, Division of Infectious Diseases. "We are optimistic that further trials on younger age groups will show similarly strong data."

URMC is participating in a clinical trial of the Moderna COVID-19

vaccine in children 6 months to 12 years of age. The study—which is being led locally by Caserta and Jennifer Nayak, M.D. – is expected to launch in the spring. Pfizer and BioNTech have started clinical [trials](#) of its [vaccine](#) in children age 5 to 10 and will expand to lower age groups in the coming months. It is anticipated that URMC will become involved in these studies in the coming months.

More information: Pfizer-BioNTech Announce Positive Topline Results of Pivotal COVID-19 Vaccine Study in Adolescents: www.pfizer.com/news/press-rele...line-results-pivotal

Provided by University of Rochester Medical Center

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