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Editorial

Efficacy of the COVID-19 Vaccine in Children Aged 5 to 11

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EDITORIAL

BioNTech have revealed new data to support their application for FDA approval of the COVID-19 vaccine in children aged 5 to 11, with a relative vaccination effectiveness of more than 90%.

Clinical data explored a 10-g vaccination dosage in children 5 to 11 years of age, which is one-third of the amount used in adults and children 16 years of age and older, according to a briefing document provided by the FDA. Although there is still a robust immunological response, this dosage decrease was chosen to reduce adverse effects (AEs).

The brief also mentioned a large increase in COVID-19 instances among youngsters in recent months, particularly amid the broad spread of the Delta variation. Researchers discovered a 419 percent rise in COVID-19 cases among youth 17 years and younger between August and September 2021 and June and July 2021, according to a press statement.

COVID-19 was also in the top 10 major causes of death for children 5 to 14 years old in the United States between January and May 2021, despite the fact that the mortality rate for children is substantially lower than that for adults.

BioNTech are requesting Emergency Use Authorisation (EUA) for a 10-g dosage of the vaccine in a 2-dose primary series given 3 weeks apart, based on these results and the clinical trial outcomes. Safety and effectiveness data, as well as a thorough Chemistry, Manufacturing, and Controls data package, are all included in the EUA application.

The immune bridging study, which compared SARS-CoV-2 neutralising antibodies in a subgroup of participants in this age range with another group of young adult participants 16 to 25 years of age, was used to infer efficacy of the 10-g dosage in children 5 to 11 years of age. The ratio of 50 percent neutralising geometric mean titers in children 5 to 11 years of age compared to persons 16 to 25 years of age was 1.04 among trial participants with no prior evidence of SARS-CoV-2 infection up to 1 month after dose 2.

The immune bridging trial was used to infer effectiveness of the 10-g dose in children 5 to 11 years of age, which compared SARS-CoV-2 neutralising antibodies in a subset of participants in this age range with another group of young adult participants 16 to 25 years of age. Up to one month after dose 2, the ratio of 50 percent neutralising geometric mean titers in children 5 to 11 years old to individuals 16 to 25 years old was 1.04 among trial participants with no prior indication of SARS-CoV-2 infection.

Safety data were collected from 2250 participants 5 to 11 years of age, including 1518 who received the vaccine and 750 who received the placebo, with a follow-up time of at least 2 months after the second dose. Supplemental safety data were also collected from an expansion group with an additional 2250 participants. At the time of the most recent data cut-off date, the expansion group had a median follow-up time of 2.4 weeks after the second dose.

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Reactogenicity was mostly mild to moderate and short-lived, with a median onset of 1 to 4 days after vaccination and resolution within 1 to 2 days after onset. Local reactions presented mostly as injection site pain, although mild to moderate redness and swelling occurred at higher frequencies in children than was previously reported.

Fatigue, headache, and muscular discomfort were among the systemic effects, which often increased in frequency or severity as the number of doses rose. These AEs, on the other hand, were often milder and less common than those previously documented in prior investigations.

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