

Overall symptoms after BNT162b2, other vaccines comparable in children under five

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Among children younger than 5 years, guardian-reported symptoms after



BNT162b2 administration were generally comparable to those for onlabel non-severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) vaccines, according to a study published online Oct. 20 in *JAMA Network Open*.

Nicole Toepfner, M.D., from the Technische Universität Dresden in Germany, and colleagues conducted a retrospective assessment of the safety of the BNT162b2 <u>vaccine</u> used off-label in children younger than 5 years compared with the safety of other vaccines in the same sample. Short-term safety <u>data</u> were presented for children receiving one to three doses of 3- to $10-\mu g$ BNT162b2. A total of 7,806 <u>children</u> were included in the study, and they were followed for a mean of 91.4 days since first BNT162b2 vaccination.

The researchers found that compared with lower doses, a 10-µg dosage was more frequently associated with local injection-site symptoms. In the active comparator analysis, the probability of any symptoms, local symptoms, musculoskeletal symptoms, dermatologic symptoms, or otolaryngologic symptoms was elevated after BNT162b2 versus non-SARS-CoV-2 vaccines (odds ratios, 1.62, 1.68, 2.55, 2.18, and 6.37, respectively), while lower probabilities of general symptoms and fever were seen after BNT162b2 (odds ratios, 0.77 and 0.42, respectively). At BNT162b2 dosages above 3 µg, symptoms requiring hospitalization were reported.

"These data may be helpful in safety considerations for individual decision-making and may add to data expected from prospective licensure studies for expert recommendations about BNT162b2 vaccinations in this age group," the authors write.

More information: Nicole Toepfner et al, Comparative Safety of the BNT162b2 Messenger RNA COVID-19 Vaccine vs Other Approved Vaccines in Children Younger Than 5 Years, *JAMA Network Open*



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