## **RESEARCH SUMMARY**

# Evaluation of BNT162b2 Covid-19 Vaccine in Children Younger than 5 Years of Age

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#### CLINICAL PROBLEM

Safe, effective Covid-19 vaccines are needed in young children to protect them from severe disease, hospitalizations, and postacute effects of Covid-19 such as multisystem inflammatory syndrome in children (MIS-C).

## CLINICAL TRIAL

**Design:** An ongoing phase 2–3, randomized, placebocontrolled trial examined the immunogenicity, safety, and efficacy of the BNT162b2 vaccine in healthy children 6 months to 4 years of age.

**Intervention:** 1776 children 6 months to <2 years of age and 2750 children 2 to 4 years of age were randomly assigned in a 2:1 ratio to receive two injections, 21 days apart, of BNT162b2 vaccine (3- $\mu$ g dose, selected during phase 1) or saline placebo; a third dose was administered  $\geq$ 60 days after the second dose. Outcomes included immunogenicity, as measured by the ratio of the geometric mean titer (GMT) of neutralizing antibodies against SARS-CoV-2 1 month after the third vaccine dose to the GMT at 1 month after the second 30- $\mu$ g dose in persons 16 to 25 years of age.

#### RESULTS

**Immunogenicity:** Immunogenicity in the children receiving the vaccine was similar to that in persons 16 to 25 years of age receiving two  $30-\mu g$  vaccine doses. Incidences of seroresponse were also similar.

**Safety:** Local reactions and systemic events were mostly mild to moderate; the frequency was generally higher after BNT162b2 than after placebo.

**Efficacy:** Observed efficacy against symptomatic Covid-19 was 73% from 7 days after the third dose.

#### LIMITATIONS AND REMAINING QUESTIONS

- The trial was not powered to assess vaccine efficacy against severe disease or specific SARS-CoV-2 variants.
- Longer-term data on immune-response duration and safety are needed.
- Most participants were White.

Links: Full Article | NEJM Quick Take







## CONCLUSIONS

In children 6 months to 4 years of age, a three-dose primary series of BNT162b2 Covid-19 vaccine was immunogenic, safe, and efficacious.