RESEARCH SUMMARY

Meningococcal ACWYX Conjugate Vaccine in 2-to-29-Year-Olds in Mali and Gambia

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CLINICAL PROBLEM

Because of mass vaccination campaigns, meningitis caused by serogroup A has been nearly eliminated in the African meningitis belt. However, high rates of disease from other serogroups persist, so an effective, affordable, multivalent meningococcal conjugate vaccine is needed.

CLINICAL TRIAL

Design: A phase 3, randomized, noninferiority trial assessed the efficacy and safety of the pentavalent ACWYX vaccine NmCV-5 among participants 2 to 29 years of age in Mali and Gambia.

Intervention: 1800 participants were randomly assigned in a 2:1 ratio to receive a single intramuscular dose of NmCV-5 or the licensed quadrivalent vaccine MenACWY-D. The objectives of the trial were to determine whether the immune responses to serogroups A, C, W, and Y generated by NmCV-5 were noninferior to those generated by MenACWY-D and whether the immune responses to serogroup X generated by NmCV-5 were noninferior to the lowest response generated by MenACWY-D. Immune responses were defined by the serogroup-specific seroresponse and the geometric mean titer (GMT) at 28 days after vaccination. Safety was also assessed.

RESULTS

Efficacy: At 28 days after vaccination, the noninferiority of the NmCV-5 vaccine to the MenACWY-D vaccine was shown for both objectives on the basis of both seroresponse and GMT.

Safety: The incidence of systemic adverse events was similar in the two trial groups, and all the events were mild or moderate in severity.

LIMITATIONS AND REMAINING QUESTIONS

- The current trial studied only immunogenicity, not efficacy in disease prevention.
- The trial did not assess whether immune responses would persist at 6 months and 12 months.
- The percentage of participants with a seroresponse for serogroup A was limited because of previous campaigns with the MenAfriVac vaccine and routine immunization programs in the region.

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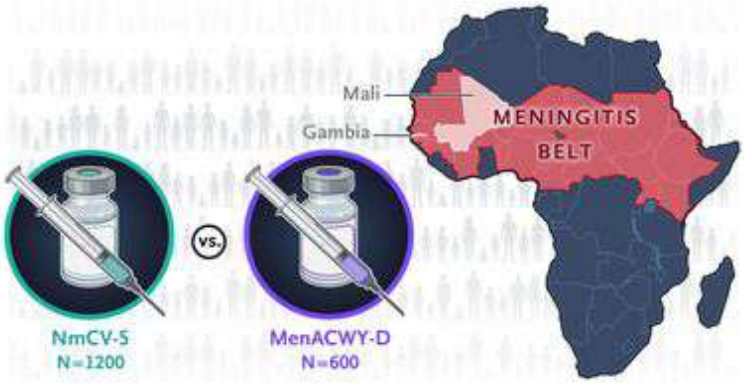

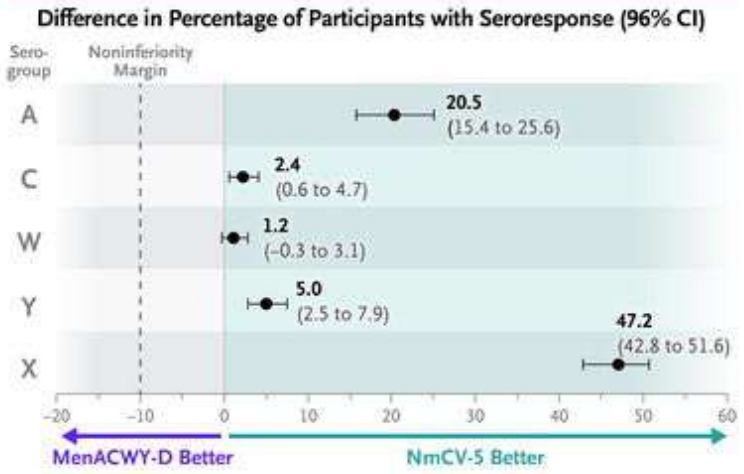

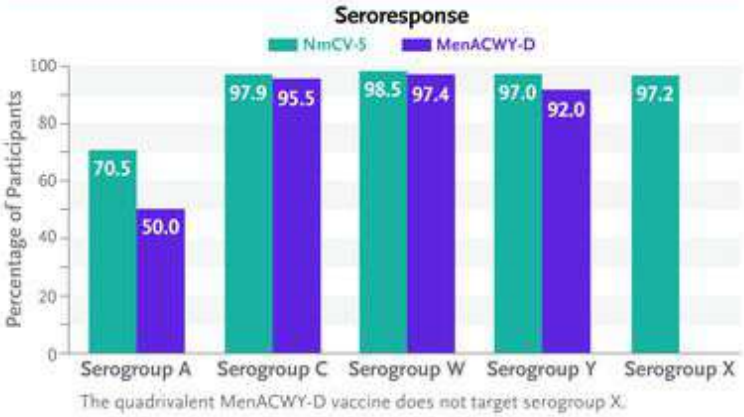

CONCLUSIONS

Among participants 2 to 29 years of age in the African meningitis belt, the meningococcal conjugate NmCV-5 vaccine was noninferior to the MenACWY-D vaccine in generating an immune response and had a similar safety profile.