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Vaccines for pneumococci, Haemophilus and meningococci

FEASIBILITY OF A SINGLE PRIMING DOSE OF THE MENINGOCOCCAL GROUP C CONJUGATE VACCINE NEISVAC-C IN INFANTS

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Objective:

Numerous clinical studies with a Tetanus-toxoid conjugated, monovalent meningococcal serogroup C vaccine, NeisVac-C, suggested that high seroprotective titers in infants can be induced with a single priming dose. The present study aimed to assess non-inferiority of seroprotection rates following a single priming dose as compared to a two-dose priming one month after the primary vaccination (rSBA ≥8), prior to the booster (rSBA ≥8), and one month after the booster (rSBA ≥128).

Methods:

956 subjects, were randomly assigned to three treatment groups to receive a single dose at 4 or 6 months of age, or two doses at 2 and 4 months of age. All subjects received a booster between 12 and 13 months of age. Concomitant vaccinations with Infanrix® hexa and Prevenar 13® were administered at all timepoints.

Results:

Rates of subjects with seroprotective antibody titers (rSBA ≥ 8) one month after primary vaccination was 99.6% in the 4 month dose group, 99.2% in the 6 month dose group, and 99.6% in the two-dose group. Prior to the booster, 78.0% and 90.7% of subjects had seroprotective antibody titers in the single dose groups (month 4 or month 6, respectively), compared to 67.8% in the two dose group. One month after the booster, > 98.5% of subjects in all three dose groups showed rSBA titers ≥ 128, with no differences between the groups.

In Spain, routine infant and catch-up meningococcal C vaccination programs are implemented since 2002, and the majority of children and young adults have been immunized, resulting in an increased level of bactericidal MenC antibodies in the population. In contrast, Poland did not routinely implement MenC vaccination and consequently, only a small proportion of the population has been vaccinated. To assess the potential impact of the different vaccination histories of the Spanish and Polish populations, subjects were evaluated separately by country and by pre-vaccination titers.
Seroprotective titers were observed at similar rates in both Spanish and Polish infants in all three study groups at all each time point. However, the fact that only a lower number of subjects were recruited at Spanish sites, i.e. 105 out of 956, does not allow drawing definite conclusions. The number of subjects who seroprotective titers at baseline was very low, 19 infants in both countries, and did not permit meaningful conclusions, although a trend towards lower seroprotection rates was observed in baseline-positive subjects.

Conclusion:

A single-dose priming at 4 or 6 months of age followed by a booster in the beginning of the second year of life is non-inferior to the currently licensed two-dose priming schedule.

Trial Registration: ClinicalTrials.gov: NCT01218451

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