A Conjugate Vaccine (MenAfriVac™) with Meningococcal ACWY Polysaccharide Vaccine in Healthy Indian Children 2-10 Years of Age


Background

Meningococcal disease (Group A N. meningitidis) is endemic in India with large, country-wide recurrent outbreaks every 8 to 10 years. Epidemiologic evidence is scarce and limited to outbreak investigations and ad hoc surveillance. Control measures in India are limited to health education, chemoprophylaxis of contact cases, and the provision of multivalent polysaccharide vaccine to high risk groups during epidemics. [1, 2, 3, 4]

The Meningitis Vaccine Project aims to eliminate epidemic meningitis through development, testing and widespread use of meningococcal conjugate vaccines. Through Phase I & II trials, a meningitis through development, testing and widespread use of meningococcal conjugate vaccines. Through Phase I & II trials, a

Methods

Observer-blind, randomized controlled trial of 340 Indian children (2 to 10 year-olds)

Test vaccine: PsA-TT—0.5ml dose contains 10 mg Ps, 10-33 mcg TT, API D adjuvant

Reference vaccine: GSK Mencevax ACWY®—0.5 ml contains 50 µg Ps A, C, W and Y

Immunologic response measured by Serum Bacterial Antibody titers (rSBA) and anti-MenPsA specific IgG (ELISA).

Safety assessed through active daily follow-up for 4 days post-vaccination, and the recording of all AEs for 28 days and SAEs for the duration of the study.

Figure 1: Study profile at 4 weeks

Table 1. Overall participant safety profile at 4 weeks post-vaccination

Table 2. Serogroup A Serum Bacterial Antibody Titres (rSBA): > 1:128 (percentage with 95% Confidence Interval) at baseline (pre-vaccination) and 28 days post-vaccination

Figure 2. Pre vaccination MenA rSBA Titres: Reverse cumulative distribution curves

Figure 3. Day 28 Post-Vaccination MenA rSBA Titres: Reverse cumulative distribution curves

Figure 4. MenA rSBA Geometric Mean Titers (GMT) Pre- and 28 days post-vaccination

Figure 5. MenA IgG (ELISA) Geometric Mean Concentrations (GMC) Pre- and 28 days post-vaccination

Findings

Fourfold increase in rSBA titers in the PsA-TT group (95.2% compared to 78.2% in the PsACWY group). This demonstrates non-inferiority of the PsA-TT vaccine to the PsACWY vaccine.

Significantly higher rSBA GMTs are observed in the PsA-TT group (11.29 vs 28.38 in the PsACWY group). Similarly, anti-MenPsA GMCs are significantly higher in the PsA-TT group (89.1% compared to 15.3 in the PsACWY group).

The percentage of subjects with a 4-fold increase in IgG ELISA is 100% in the PsA-TT group and 97.6% in the PsACWY group (at 28 days compared to baseline). The percentage of subjects with a 2 µg/ml in IgG ELISA is 100% in the PsA-TT group and 91.2% in the PsACWY group (at 28 days).

The safety profile is similar in both groups except for tenderness (30% in the PsA-TT group compared to 12% in the PsACWY group).

Conclusions

The new PsA-TT conjugate vaccine is highly immunogenic and is as safe and well tolerated as a licensed and widely used Ps vaccine.

References