Virol Mycol 2018, Volume 7
DOI: 10.4172/2161-0517-C3-030

Safety and immunogenicity of new cuban pneumococcal conjugate vaccine

María E Toledo-Romaní[1], Nivaldo Linares[2], Maria F. Casanova[3], RInaldo Puga-Gómez[4], Carlos P Dotres[5], Beatriz Paredes[2], Darielys Santana[2], Dagmar García-Rivera[2], Yury Valdés-Balbin[2], V. Verez-Bencomo[2], Laura Rodriguez-Noda[2]

[1]Tropical Medicine Institute "Pedro Kourí", Cuba
[2]Finlay Vaccine Institute, Cuba
[3]University Pediatric Hospital "Paquito González Cueto". Cuba
[4]International Clinic "Cira García. Cuba
[5]Pediatric Hospital "Juán Manuel Márquez", Cuba

Background and Aims: A new pneumococcal conjugate vaccine is currently undergoing advanced clinical evaluation in Cuba. We present the safety and immunogenicity current results of clinical research of PCV7-TT.

Methods: PCV7-TT contains 2µg of capsular polysaccharide from serotypes 1, 5, 14, 18C, 19F and 23F and 4µg of 6B conjugated to tetanus toxoid (TT). The results of three randomized control trials are synthetized to demonstrated the safety and immunogenicity including: 1) adults (n=40), 2) preschool children 4-5y/o (n=15) and infants 7-11 months (n=30) and 3) preschool children 1-5y/o (n=1135). The infants and preschool children were followed for 30 days after each doses to assess adverse events. Serum was obtained 30 days after the second and third dose for evaluating the immunogenicity. Serotype specific OPA and ELISA were performed at the WHO Reference Laboratory, UCL Institute of Child Health.

Results: No serious adverse events were reported in none group of age. Following a single-dose in 4–5-year-old children and infants vaccinated at 7, 8 and 11 months induced statistically significant ($p \leq 0.05$) increase of IgG GMC and OPA for seven common serotypes with Synflorix® as control vaccine. New insights since a protective efficacy clinical trial including 1135 preschool children and using PREVNAR® as control vaccine, showing that more than 90% of children have IgG titers ≥0.35 for 6 of 7 vaccine serotypes, and more than 77% for serotype 5.

Conclusions: The Cuban pneumococcal vaccine candidate is safe and immunogenic. This results are useful to support the decision-making to introduce the new vaccine in Cuba.

nlinares@finlay.edu.cu