S5

Safety and Immunogenicity of Tetanus-Diphtheria-Acellular Pertussis Vaccine (Tdap) During Pregnancy

S. Halperin, B. Halperin, V. M. Allen, J. Langley, S. McNeil, L. Li, D. MacKinnon-Cameron for the Canadian Tdap Pregnancy Investigator Group
Dalhousie University, Halifax, Nova Scotia, Canada

Objective: Explain the antibody response to the primary pertussis vaccine series of infants whose mothers received Tdap during pregnancy.
Background: Immunization of women during pregnancy with Tdap is recommended to provide protection against pertussis to the newborn infant; however, this intervention has not been well studied.
Methods: We undertook a randomized, controlled clinical trial to measure the safety, reactogenicity, and immunogenicity of Tdap given during pregnancy, the transplacental passage of antibody, and the effect of maternal immunization with Tdap on the infant's immune response to the primary immunization series with diphtheria-tetanus-acellular pertussis-inactivated-poliovirus-Haemophilus influenzae-b vaccine. A total of 273 women were enrolled in the study, randomly allocated to receive either Tdap or Td in the third trimester, delivered infants, and provided samples for the safety and immunogenicity analyses; 261 infants provided serum specimens for the immunogenicity analysis.
Results and Conclusion: Both Tdap and Td were well-tolerated during pregnancy; rates of adverse events were similar in both groups. There were 76 serious adverse events (29 for women, 47 for infants) uniformly distributed by group: 73 were unrelated; 2 were possibly related; 1 was probably related. Antibodies against pertussis toxin (PT), filamentous hemagglutinin (FHA), pertacin (PRN) and fimbriae (FIM) were elicited in the women and transferred across the placenta; infants of Tdap recipients had cord blood levels that were 21% higher than maternal levels for PT, 13% higher for FHA, 3% higher for PRN, and 7% higher for FIM. Infants whose mothers received Tdap during pregnancy had significantly higher PT antibody levels at birth and 2 months of age (pre dose 1) and significantly higher FHA, PRN, and FIM antibodies at birth, 2, and 4 months of age (pre doses 1 and 2). Infants of Tdap immunized mothers had significantly lower PT and FHA antibody levels at 6 and 7 months of age and significantly lower PRN and FIM antibody levels 7 months of age. At 7 months, the Tdap/Td antibody ratio for infants was 0.74 for PT, 0.60 for FHA, 0.59 for PRN and 0.40 for FIM. This study demonstrated that Tdap is well-tolerated during pregnancy and results in higher levels of antibodies early in infancy but lower levels after the primary series. The higher levels at birth may provide protection during the highest risk of severe pertussis in the immediate postnatal period but this may be at the expense of increased susceptibility during the second half of the first year of life.

References:

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S6

GEN-003, a Therapeutic Vaccine for Genital Herpes, Significantly Reduces Anogenital Lesion Rates and Mucosal HSV-2 Shedding

J. Flechtner, **S. Hetherington**, S. Tasker
Genocea Biosciences, Cambridge, MA

Objective: Describe the safety and efficacy of GEN-003, a novel herpes immunotherapy, in patients with recurrent genital herpes.
Background: Genital herpes is a lifelong infection associated with repeated outbreaks of painful genital ulcers and significant psychological distress. Daily antiviral treatment reduces outbreaks, but has only moderate effect on transmission. Episodic treatment, taken by majority of patients, has no effect on asymptomatic shedding between outbreaks, which is believed to the source of most new infections. Multiple previous efforts to develop vaccines for herpes, usually focused on eliciting antibody, have met with failure. GEN-003, a genital herpes