Postlicensure surveillance for pre-specified adverse events following the 13-valent pneumococcal conjugate vaccine in children.

No significant increased risk of pre-specified adverse events following PCV13.

An increased risk for encephalopathy was not confirmed by medical record review.

The association between PCV13 and Kawasaki disease needs further investigation.
Abstract

Although no increased risk was detected for serious adverse events in the prelicensure trials for the 13-valent pneumococcal vaccine, Prevnar 13® (PCV13), continued monitoring of rare but serious adverse events is necessary. A surveillance system using cohort study design was set up to monitor safety of PCV13 immediately after it was included in the childhood immunization program in the United States. The exposed population included children of 1 month to 2 years old who received PCV13 from April, 2010 to January, 2012 from the eight managed care organizations participating in the Vaccine Safety Datalink Project in the United States. The historical unexposed population was children of the same age who received the 7-valent pneumococcal conjugate vaccine Prevnar 7® (PCV7) in 2007 (or 2005 depending on the outcome of interest) to 2009. The risk of pre-specified adverse events in the risk window following PCV13 was repeatedly compared to that in the historical comparison group. The number of doses included in the study was 599,229. No increased risk was found for febrile seizures, urticaria or angioneurotic edema, asthma, thrombocytopenia, or anaphylaxis. An increased risk for encephalopathy was not confirmed following the medical record review. The relative risk for Kawasaki disease in 0–28 days following vaccination was 1.94 (95% confidence interval: 0.79–4.86), comparing PCV13 to PCV7. Comparing to PCV7 vaccine, we identified no significant increased risk of pre-specified adverse events in the Vaccine Safety Datalink study cohort. The possible association between PCV13 and Kawasaki disease may deserve further investigation.

Keywords

Pneumococcal conjugate vaccine; Vaccine safety; Surveillance; Group sequential analysis

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