CONCOMITANT ADMINISTRATION OF LIQUID PORCINE CIRCOVIRUS-FREE HUMAN ROTAVIRUS VACCINE WITH ROUTINE PEDIATRIC VACCINES DOES NOT IMPACT IMMUNE RESPONSES IN INFANTS: RESULTS FROM A PHASE 3, RANDOMIZED TRIAL IN THE UNITED STATES

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BACKGROUND AND AIM

- Porcine circovirus type 1 (PCV-1) material was detected in the human rotavirus vaccine (*Rotarix*, GSK)[1]
- Although no safety risk was identified for infants vaccinated with *Rotarix*, a PCV-free vaccine (no detection of PCV-1 and PCV-2 according to the limit of the tests used) was developed, with comparable immunogenicity and safety profile to the initial *Rotarix*[1,2]
- **We assessed the immunogenicity and safety of routine vaccines when (co-)administered with PCV-free *Rotarix* liquid (Liq) or *Rotarix* lyophilized (Lyo) in infants**

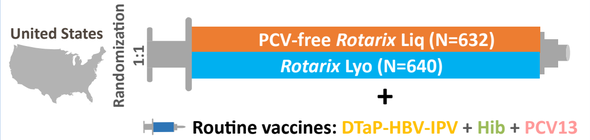
KEY MESSAGES

- Routine vaccines (co-)administered with PCV-free *Rotarix* Liq showed non-inferior immune responses and similar safety profiles compared to (co-)administration with *Rotarix* Lyo

✓ Routine vaccines have similar immunogenicity and safety profiles when administered with either PCV-free *Rotarix* Liq or *Rotarix* Lyo in infancy
✓ PCV-free *Rotarix* Liq could be used as part of routine vaccination in the United States

METHODS

Phase 3, randomized, single-blind trial (NCT03207750)



Time point	Day 1	Month 2	Month 4	Month 5	Month 10
Age of infants	6–12 weeks	~4 months	~6 months	~7 months	~12 months

Adverse events (AE)
- Solicited general AEs (Days 1–8)
- Unsolicited AEs (Days 1–31)
- Serious AEs (SAEs)

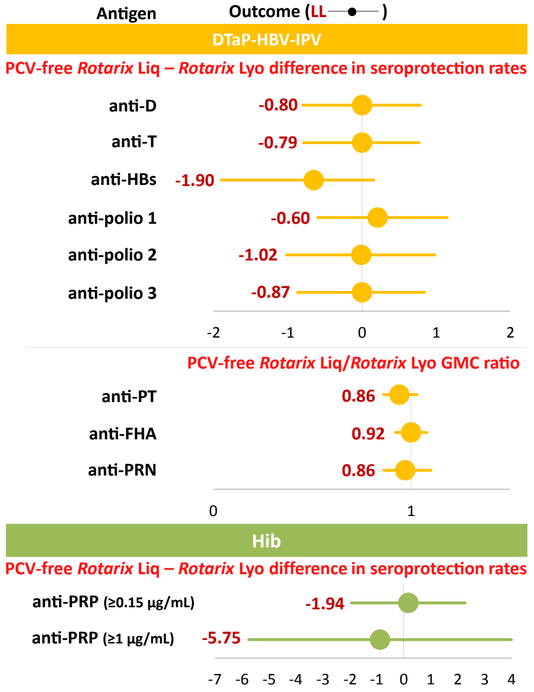
Primary endpoints:
- **Non-inferiority** of immune responses to routine vaccine antigens (co-) administered with PCV-free *Rotarix* Liq *vs Rotarix* Lyo
- **Rule out a 10% decrease** in seroresponse to pertussis antigens (co-) administered with PCV-free *Rotarix* Liq *vs Rotarix* Lyo

N, number of infants in the exposed set (at least one vaccine dose administered); DTaP-HBV-IPV, diphtheria-tetanus-acellular pertussis, hepatitis B virus and inactivated poliovirus vaccine; Hib, monovalent *Haemophilus influenzae* type b vaccine; PCV13, 13-valent pneumococcal conjugate vaccine.

- Demographic characteristics were comparable between groups (scan for more details)

RESULTS

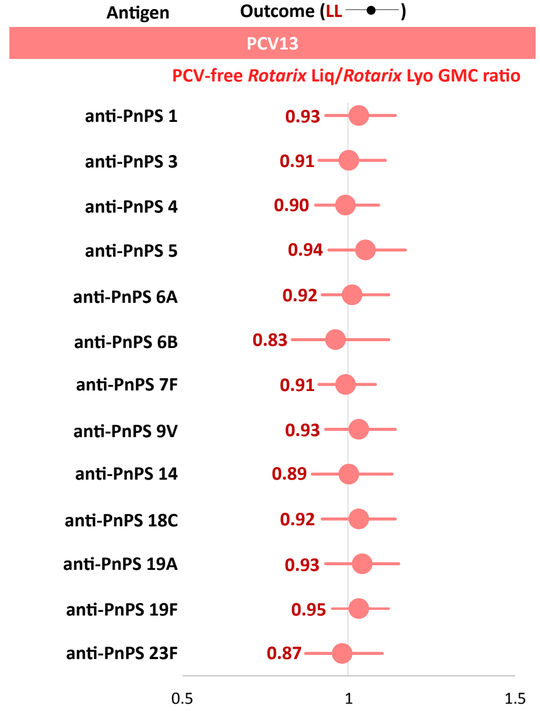
Immune responses to routine vaccine antigens were not inferior for (co-)administration with PCV-free *Rotarix* Liq *vs* (co-)administration with *Rotarix* Lyo



A 10% decrease in seroresponse to PT, FHA and PRN antigens when DTaP-HBV-IPV was co-administered with PCV-free *Rotarix* Liq compared to when DTaP-HBV-IPV was co-administered with the currently licensed *Rotarix* Lyo was ruled out*

Per-protocol set. LL, lower limit of the 95% confidence interval; **HBs**, hepatitis B surface antibody; **GMC**, geometric mean concentration; **PT**, pertussis toxoid; **FHA**, filamentous hemagglutinin; **PRN**, pertactin; **PRP**, polyribosyl-ribitol phosphate. ***Scan** for more details.

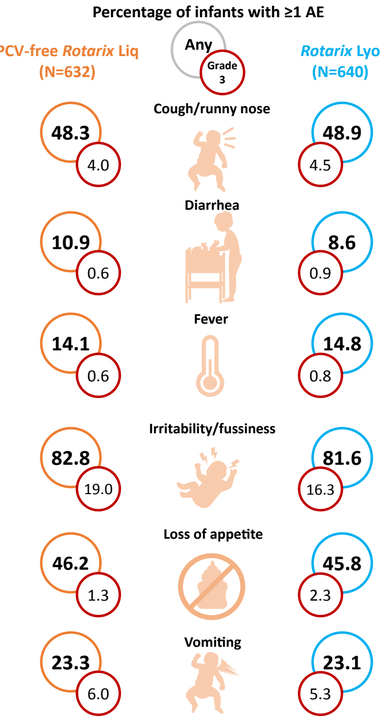
Non-inferior immune responses to pneumococcal antigens were demonstrated for (co-)administration with PCV-free *Rotarix* Liq *vs* (co-)administration with *Rotarix* Lyo



Per-protocol set. PnPS, pneumococcal capsular polysaccharide.

- Seroprotection/seropositivity rates were ≥99.3% for all DTaP-HBV-IPV antigens, ≥97.4% for Hib and ≥90.8% for most PCV13 serotypes
- Geometric mean concentrations/titers for the routine vaccine antigens were comparable between groups (scan for more details)
- The percentage of infants with anti-rotavirus antibody concentration ≥20 U/mL was similar between PCV-free *Rotarix* Liq (76.3%) and *Rotarix* Lyo (78.9%)

The incidence of solicited AEs was similar in the two groups



Exposed set. N, number of infants with at least one documented dose; **any fever**, ≥38.0°C.
Scan for definition of Grade 3 AEs.

Similar incidence of unsolicited AEs and SAEs was observed between groups

- 75 SAEs: 2 (*Rotarix* Lyo: abdominal distension; intussusception) considered vaccine-related by the investigator, both resolved within 2 days; 1 fatal SAE (PCV-free *Rotarix* Liq: sudden infant death syndrome) considered non-vaccine-related by the investigator

References: 1. Dubin G, et al. Hum Vaccin Immunother. 2013;9:2398–408; **2.** Salamanca de la Cueva I, et al. J Infect Dis. 2020. Epub ahead of print (doi: 10.1093/infdis/jiaa210).

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Trademark statement: Rotarix is a trademark owned by or licensed to the GSK group of companies.

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