

ORAL ABSTRACTS

1335. Transfer and Persistence of Antibodies in Infants Following Maternal Immunization with an Investigational Trivalent Group B *Streptococcus* Vaccine

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Background. Group B Streptococcus (GBS) is a serious cause of meningitis and sepsis in young infants. We assessed maternal immunization with an investigational trivalent GBS polysaccharide-CRM conjugate vaccine, with follow-up of both mothers and infants (clinicaltrials.gov NCT01446289).

Methods. In a phase II, observer-blind, placebo-controlled study, 86 pregnant women were enrolled at 24–35 weeks gestation and randomized 3:2 to receive intramuscular placebo (saline) or trivalent GBS vaccine containing 5 µg of glycoconjugates of each of GBS serotypes Ia, Ib and III. GBS serotype-specific antibodies were measured in mothers pre- and Day 31 post-immunization, and in mothers and infants at delivery and Day 91 post-partum. Safety was assessed up to at least 5 months postpartum.

Results. Of 86 pregnant women enrolled (age 29.8 ± 5.1 years, mean ± SD), 51 received vaccine and 35 placebo at 30.0 ± 3.3 weeks gestation. Low pre-immunization antibodies against serotypes Ia, Ib and III increased 16-, 23- and 20-fold, respectively, at delivery. Among maternal-infant pairs with detectable antibodies, placental transfer was 81% (n = 38), 70% (n = 35) and 65% (n = 33), against serotypes Ia, Ib and III. Infants of vaccinated mothers had increased antibody levels at birth which persisted above placebo group levels through day 91 of age.

Mild or moderate solicited reactions were reported in 54% and 53% of vaccine and placebo groups, respectively, with no vaccine-related SAEs reported.

Conclusion. One dose of trivalent GBS vaccine was well-tolerated with no concerning safety signals in pregnant women, and induced increased antibody concentrations in mothers and their infants.

Disclosures. S. A Halperin, Novartis Vaccines: Investigator, Consulting fee G. Donders, Novartis Vaccines: Investigator, Consulting fee R. Devlieger, Novartis Vaccines: Investigator, Consulting fee S. Baker, Novartis Vaccines: Employee, Salary P. Forte, Novartis Vaccines: Employee, Salary F. Wittke, Novartis Vaccines: Employee, Salary K. Slobod, Novartis Vaccines: Employee, Salary P. M Dull, Novartis Vaccines: Employee, Salary

GBS Serotype Study Group	Ia			Ib			III		
	N	GBS	Placebo	N	GBS	Placebo	N	GBS	Placebo
Mothers									
GMC - Delivery									
[95% CI]									
Infants									
GMC - Birth									
[95% CI]									
Infants									
GMC - 91 days									
[95% CI]									
	51	5.22 [3.37, 8.1]	35 0.37 [0.22, 0.63]	51	2.41 [1.48, 3.94]	35 0.13 [0.07, 0.23]	51	1.90 [1.15, 3.12]	35 0.11 [0.06, 0.19]
	35	5.14 [2.64, 10]	25 0.33 [0.15, 0.71]	31	2.93 [1.14, 7.57]	20 0.1 [0.03, 0.32]	30	1.93 [0.82, 4.59]	22 0.07 [0.02, 0.18]
	35	1.28 [0.76, 2.16]	25 0.25 [0.13, 0.46]	35	0.54 [0.25, 1.19]	25 0.06 [0.03, 0.16]	35	0.43 [0.21, 0.86]	25 0.07 [0.03, 0.15]