Abstract Title: Child development after exposure to monoclonal antibodies during breastfeeding

Press Release Title: Good News—MS Drugs Taken While Breastfeeding May Not Affect Child Development

Authors: Laura Witt¹, Sandra Thiel¹, Ralf Gold², Kerstin Hellwig³
¹Department of Neurology, St. Josef Hospital, Ruhr University, Bochum, Germany, ²Neurologische Universitätsklinik, ³St. Josef Hospital Bochum

Objective: To analyze how infants breastfed under monoclonal antibodies (mAb) develop during the first 36 months of life

Background: Most mAbs used to treat multiple sclerosis (MS) are not approved for use during lactation. Studies on excretion of other mAbs used in MS therapy show low transfer into breast milk and no adverse effects on exposed infants, but clinical data are limited.

Design/Methods: Live births with (≥1 day) or without mAb exposure during breastfeeding and ≥6 months follow-up were identified in the German MS and Pregnancy Registry. Primary outcomes (hospitalizations, systemic antibiotic use, developmental delay, weight at follow-up visits) were compared between breastfed mAb-exposed (exposed group) and unexposed (control group) infants. We matched groups for disease modifying therapy exposure during pregnancy and performed adjusted linear, logistic and poisson regression analyses.

Results: We identified 183 mAb breastfed exposed cases (median follow-up 1 year, range 0.5-3) with a diagnosis of MS (n=180) or neuromyelitis optica spectrum disease (n=3), with no significant differences in demographic characteristics compared to the control group (n=183).

MAB exposure during breastfeeding started on median day 19 (range 0-293) postpartum (median duration 172 days, range 2-1104). Natalizumab (n=125/68.31%) was most commonly used, followed by ocrelizumab (n=34/18.58%), rituximab (n=11/6.01%), and ofatumumab (n=10/5.46%); therapy was switched from natalizumab to ocrelizumab in 2 cases (1.09%), from rituximab to ocrelizumab in 1 case (0.55%) while breastfeeding. Three children had been previously breastfed on glatiramer acetate and two on interferons.

Adjusted regression analyses showed no association of annual hospitalization (rate ratio 1.23; 95% confidence interval [CI] 0.70,2.16; p 0.473), annual systemic antibiotic use (rate ratio 1.55; 95%CI 0.93,2.57; p 0.093), developmental delay (odds ratio [OR] 1.16; 95%CI 0.52,2.60; p 0.716), or weight at follow-up visits with mAb-exposed breastfeeding.

Conclusions: Our data show that mAb exposure during breastfeeding had no negative effect on the development or health of breastfed infants.

Study Support: The German MS and pregnancy registry is partly supported by the Innovation Fund of the Federal Joint Committee, Almirall Hermal GmbH, Biogen GmbH Germany, Hexal AG, Merck Serono GmbH, Novartis Pharma GmbH, Roche Deutschland GmbH, Sanofi Genzyme and Teva GmbH.