during pregnancy was 1.05 IC95% 0.96–1.15 in the crude analysis and 1.03 Cl95% 0.93–1.16 in the adjusted analysis. The relative risk of taking ibuprofen was 1.17 Cl95% 0.91–1.51 in the crude analysis and 1.16 IC95% 0.91–1.48 in the adjusted analysis. No association was found when analyzing the simultaneous use of paracetamol and ibuprofen during the pregnancy. When analyzing the children's exposures to the medicines at 12 and 24 months, we observed a significant association with the use of paracetamol and ibuprofen: relative risk of 1.11 Cl95% 1.01–1.23 and 1.16 Cl95% 1.04–1.30 in the adjusted analysis, respectively.

Conclusions: the findings suggest that there is no association between prenatal exposure to paracetamol and ibuprofen and increased risk of developing asthma at 24 months. However, the use of paracetamol and ibuprofen from birth to 24 months of age increased the risk of asthma in the children.

771 | Use of iron salts, hemoglobin levels in gestation and the development of diabetes mellitus Gestacional in the 2015 Pelotas birth cohort, Brazil

Vanessa IribarremAvena Miranda¹; Tatiane da Silva Dal Pizzol²; Marysabel PintoTellis Silveira¹; Sotero Serrate Mengue²; Mariângela Freitas Silveira¹; Andréa Dâmaso Bertoldi^{1,3}

¹ Federal University of Pelotas, Pelotas, Brazil; ² Federal University of Porto Alegre, Porto Alegre, Brazil; ³ Harvard Medical School and Harvard Pilgrim Health Care Institute, Boston, MA

Background: Prophylactic iron supplementation in pregnant women is a universal practice of antenatal care. However, there is evidence that high iron intake increase the risk of gestational diabetes mellitus (GDM) for women with hemoglobin levels >11 g/dL in early pregnancy.

Objectives: To evaluate the association between the use of iron salts in pregnant, hemoglobin levels, and development of GDM.

Methods: Longitudinal study with women who participated in the perinatal study (n = 4270) in 2015 Pelotas Birth Cohort, Brazil. Participants were interviewed at the maternity about the antenatal period. The analyzes were performed with all non-anemic women before the 24th week of gestation (n = 2463). The GDM outcome was based on maternal self report. All women with a previous history of diabetes were excluded. The exposure "use of prophylactic iron in the first or second trimester of gestation", was defined as iron use in non-anemic pregnant women. In order to characterize this exposure, was used the variable of use of vitamins and salts of iron in the gestation. It was considered "yes" for the use of iron all the compounds with ferrous sulfate and all the vitamins with iron. Descriptive analyses were performed between exposed and unexposed and factors associated with the development of GDM were evaluated using Poisson regression with robust variance. Variables with p < 0.2 were included in adjusted analysis. The regression followed a hierarchical backward selection model. The distal level included socio-demographic variables and family history of diabetes; the second level includes pre-gestational body mass index (BMI), parity and smoking; and proximal level included the use of iron salts. The significance level was set at 0.05. **Results:** Younger non-anemic women (19 years or younger) used more iron salts (79.4%) than older women (71.0%, p=0.02). Sociodemographic characteristics, pre-gestational BMI, parity, smoking and family history of diabetes did not show statistically significant differences. The adjusted analysis did not find association between the use of iron salts and the risk of GDM (Risk relative = 1.0, 95%CI 0.7–1.4).

Conclusions: Prophylactic supplementation of iron salts in non-anemic pregnant women is not a risk factor for GDM. To confirm our results, future studies should include baseline hemoglobin levels and additional markers of iron status.

772 | Safety outcomes among infants exposed to Omalizumab via breastfeeding: Results from the Xolair pregnancy registry (EXPECT)

Sandra Lopez Leon¹; D.g. Kaufman²; M. Howard²; S. Mukhopadhyay³; Robert Fogel¹

¹ Novartis Pharma, East Hanover, NJ; ² Genentech, Inc, South San Francisco, CA; ³ Novartis Pharma AG, Basel, Switzerland

Background: EXPECT is an observational study with the primary objective of evaluating pregnancy outcomes in women exposed to

Objectives: Explore the potential risk to newborn infants exposed to Xolair via breast milk within the EXPECT pregnancy registry.

Methods: This analysis report on safety outcomes for 230 infants born to these women and for whom data were available on breastfeeding status and long-term outcomes. Data on infant outcomes were collected from the mother and relevant healthcare providers at 6 and 12 months after delivery (follow-up was extended to 18 months after delivery if the mother continued Xolair treatment while breastfeeding). Outcomes of interest were serious and non-serious adverse events, infections (used as a potential proxy for immune system development) and thrombocytopenia. Analyses were descriptive and results summarized as percentages.

Results: Among the 230 infants included in the analysis, 44 were not breastfed, 154 were exposed to Xolair through breastfeeding, and 32 were breastfed without being exposed to Xolair. The overall frequency of Serious Adverse Events (SAEs) reported was similar across the 3 groups: 54.5%, 48.1% and 46.9% respectively. The most frequently reported SAEs not related to infections were conditions identified in the immediate perinatal period (most common: prematurity, jaundice, and fetal distress syndrome) and minor congenital anomalies (most common: ankyloglossia, dacryostenosis, and hydrocele). The frequency of reported SAEs categorized as "infections and infestations" was 11.4%, 10.4% and 12.5% respectively. There was only one infant diagnosed with thrombocytopenia, identified on her day of birth.

Conclusions: The results of this analysis are not suggestive of a relationship between Xolair exposure via breastfeeding and an increased risk of overall adverse events or deficiencies in immune system function in infants. Limitations of the data include the observational nature of the registry, and the potential for under-reporting of infections, particularly those that were clinically mild.

773 | Prenatal drug exposure in children using psychiatric care: A study conducted in the POMME cohort

Justine Benevent; Mélanie Araujo; Caroline Hurault-Delarue; Jean-Louis Montastruc; Isabelle Lacroix; Christine Damase-Michel

Laboratoire de Pharmacologie Médicale et Clinique, UMR INSERM 1027, CIC INSERM 1436, Faculté de Médecine de l'Université Paul-Sabatier et Centre Hospitalier Universitaire, Toulouse, France

Background: More and more studies suggest a potential impact of prenatal drug exposure, in particular to psychotropic medicines, on the occurrence of neuropsychiatric disorders in the offspring.

Objectives: This study aimed to describe prenatal drug exposure in children receiving psychiatric care.

Methods: The study was conducted using the POMME cohort (PrescriptiOn Médicaments Mères Enfants), which holds anonymous medical information as well as drug and healthcare reimbursements to more than 8,000 children, from the day of their conception. The children recorded in POMME were born between July 2010 and June 2011, thus they have reached 7 years of age. Data included i) drugs and medical care reimbursements to children and their mothers during pregnancy and ii) health certificates at birth, 9 and 24 months. Children were included if they i) consulted at least once a psychiatrist, neurologist or psychiatrist, ii) presented at least two signs of psychomotor development disorders mentioned in their health certificates and/or iii) were prescribed at least one psychotropic medicine (ATC classes N05 and/or N06).

Results: A total of 1,785 children were included (21.3% of the POMME cohort). Among them, 442 (24.8%) consulted a neuropsychiatrist, neurologist or psychiatrist, 856 (48.0%) presented at least two signs of psychomotor development disorders and 670 (37.5%) were prescribed psychotropic medicines. Children were prescribed 10.4 ± 6.2 medicines during intrauterine life (versus 9.8 ± 6.1 in the entire POMME cohort) and they were mostly exposed to medicines for the digestive system during their intra-uterine life. 68.6% were prenatally exposed to nervous system drugs (67.1% in the POMME cohort), the majority of whom was exposed to analgesic. Prenatal exposure to psycholeptics and psychoanaleptics concerned 6.3% and 2.4% of the children respectively (4.8% and 1.9% in the POMME cohort) and exposure was higher during the first trimester of

Conclusions: More than two thirds of the children using psychiatric care were prenatally exposed to nervous system drugs. A case-control study nested in the POMME cohort will assess the association

774 | Antibiotic use during pregnancy and infancy and the possible impact on

overweight in early childhood. Analysis from

between neuropsychiatric disorders in the offspring and prenatal

Andrea Bertoldi¹; Thaynã Flores¹; Isabel Emmerick²; Alexandra Boing³; Mariângela Silveira¹

2015 Pelotas birth cohort, Brazil

exposure to psychotropic drugs.

¹ Federal University of Pelotas, Pelotas, Brazil; ² University of Massachusetts Medical School, Worcester, MA; ³ Federal University of Santa Catarina, Florianópolis, Brazil

Background: Antibiotics alter the composition of intestinal microbiota, even after discontinuation of use, influencing metabolic programming. There are indications that intestinal microbiota may play a role in the development of obesity. Some studies suggest that antibiotic use may influence negatively weight gain in childhood. However, few studies have examined this association during gestation and the first years of life. Thus, the best knowledge can contribute to clarify this possible association.

Objectives: To evaluate the association between antibiotic exposure in pregnancy and infancy and overweight in the first childhood through body mass index (BMI).

Methods: Longitudinal cohort study of children born in 2015 in Pelotas (Brazil), whose mothers lived in the urban area of the city. Data of this study are from the hospitalization to the delivery (perinatal study), and from the follow-ups of three, 12 and 24 months of the children. The use of antibiotics (ATC/DDD level 1 group J) was self-reported during pregnancy, at three, 12 and 24 months of the children. Variables of cumulative exposure to antibiotics was constructed for each outcome period. The outcomes (at three, 12 and 24 months) were operationalized by the BMI in z-score according to WHO parameters (\leq -2dp to >2dp: low weight/eutrophic; \geq 2dp: overweight). The weight and height of the children were measured in all follow-ups by standard interviewers.

Results: Our cohort comprised 4,014 children at the 24 months follow-up. 71.9% of mothers with skin color white, 47.1% with age between 20 and 29 years old, 34.1% with 9 to 11 years of study, about 20.0% with low income, and 44.5% were primiparous. Tobacco use was observed in 16.5%. The prevalence of use of antibiotics by mothers during pregnancy was 43.4%. The prevalence of use of antibiotics in children was 3.1%, 10.0%, 8.9% at 3 months, 12 months and 24 months, respectively. The prevalence ratio of cumulative exposures to antibiotics at the 3 months was PR = 1.24 (95%CI 0.87; 1.77), at 12 months it was PR = 1.14 (95%CI 0.96; 1.34) and at 24 months PR = 1.04 (95%CI 0.83; 1.30). The use of antibiotics at 3 months,12 months and 24 months, as well as during pregnancy, were not statistically associated with an increase in BMI.