however, there was no difference between the natalizumab-exposed and diseased-matched groups.

**Conclusion:** This is the first prospective controlled study of natalizumab exposure in pregnancy, suggesting no increase in risk for major malformations. The benefits of natalizumab continuation must be weighed against high-dose steroid treatment these women would need upon relapse following discontinuation. Natalizumab does not appear to increase the baseline risk for major malformations in exposed pregnancies. Further studies are needed for long-term effects in these exposed children.

**12. Pregnancy Outcome after In Utero Exposure to Baclofen: An ENTIS Collaborative Study**

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**Background:** Baclofen, a drug indicated to alleviate spasticity, has recently obtained in France a temporary recommendation for use in alcohol-dependent patients. Reprotoxicity studies in rats at high doses evidenced omphalocele, microcephaly, and vertebral arch widening, whereas other animal studies and isolated human cases reported no teratogenicity. The primary objective of this study was to assess the rate of major malformations.

**Methods:** Data prospectively collected by 6 European Teratogen Information Services and 16 French Pharmacovigilance Centers were used. Inclusion criteria were baclofen exposure at any time between weeks 4 and 12 of pregnancy. Each patient was matched to three controls with non-teratogenic exposure, according to age, gestational age at inclusion, year of counseling, and Teratology Information Service or country.

**Results:** Data were obtained from 134 baclofen-exposed women and 400 controls. Baclofen was used for neurologic diseases in 92.5% of patients (median oral dose: 30 mg/d, interquartile range [IQR], 10–50) and in eight alcoholic patients (median dose, 95 mg/d; IQR, 60–127.5). Compared to controls, the rates of live birth (77.6% in the baclofen and 88.7% in the control group) and miscarriage (7.4% vs. 7.7%) were similar, but elective terminations were more frequent in baclofen-exposed patients (14.9% vs. 4.2%), including one after diagnosis of anencephaly. Four additional cases of major malformations were observed in the baclofen group: sub-umbilical omphalocele with cerebral posterior fossa cyst, neck hygroma, bilateral talipes; tracheal cavernous hemangiom; bilateral kidney duplication; bilateral cleft. The rate of major malformation was higher in the baclofen group (5/104, 4.8%) compared to controls (4/330, 1.2%) (odds ratio, 4.11; 95% confidence interval, 1.08–15.62). Outcomes of alcoholic patients were voluntary abortions in two, miscarriage in one, and deliveries in five (four healthy babies and premature twins with inguinal hernia in both). Among 34 neonates exposed to baclofen until delivery, 4 (11.8%) exposed to high-dose baclofen (50–90 mg) plus concomitant psychotropic drugs developed symptoms consistent with drug exposure and/or withdrawal.

**Conclusion:** This study shows an increased risk of malformation after baclofen exposure, with central nervous system and gastrointestinal malformations reminiscent of anomalies observed in animal studies. Owing to our small sample size, further studies are needed to confirm these results.

**13. Acetaminophen Exposure during Pregnancy and Childhood Asthmatic Symptoms: Results from the Norwegian Mother and Child Cohort Study (MoBa) Cohort Study**

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**Background:** Reports on associations between prenatal acetaminophen exposure and asthma later in life remain conflicting. Our aim was to investigate a possible association between prenatal acetaminophen exposure during the third trimester and childhood asthmatic symptoms.

**Methods:** The Norwegian Mother and Child Cohort Study (MoBa) and the Medical Birth Registry of Norway (MBRN) were linked via the maternal personal identification number to obtain information on the required exposures (acetaminophen) outcomes (childhood asthmatic symptoms referred to a specialist at 18 months), and possible confounding factors (maternal medical and socio-demographic characteristics, environmental exposures, and