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humans, data on lacosamide exposure in pregnancy are still very limited.

Methods: Evaluation of antiepileptic treatment pattern and pregnancy outcomes of 52 prospectively ascertained pregnancies with lacosamide exposure collected by the Berlin Embryotox pharmacovigilance center between 2008 and 2018.

Results: The first pregnancy with lacosamide treatment was reported to our institute only one year after marketing authorization. Exposure to lacosamide during the 1st trimester was noted in 50/52 pregnancies. The median lacosamide dose was 300 mg/d (IQR 200–400 mg/d). Treatment throughout pregnancy was required in 31 out of 40 pregnancies with live born infants (78%). Median gestational week of discontinuation in the remaining nine pregnancies was 7 + 5 (IQR 5 + 4 – 9 + 2). Pregnancy outcomes of the 52 prospectively ascertained lacosamide-exposed pregnancies were three spontaneous abortions, 8 elective terminations of pregnancy (ETOP), one stillbirth and 40 live births (including one pair of twins). The median gestational week at birth was 38 + 6 (IQR 37 + 6–40 + 2, n = 39). There were three premature births (8%). The median birth weight was 3165 g (IQR 2850–3634 g, n = 40). Birth weights standardized for sex and gestational age were within the normal range (median SDS -0.05; IQR -0.59–0.60; birth weight percentiles based on Voigt et al., 2014). Three birth defects were observed: one neonate with an ASD II (or PFO) and mild coarctation of the aorta, one neonate with an anomaly of the aortic arch (concomitant VPA exposure) and one fetus with complex malformations after first trimester valproate exposure and initiation of lacosamide in the second trimester (ETOP in gestational week 21).

At conception, only 12% of women had received antiepileptic monotherapy (6/52), 58% (30/52) were on two and 31% of women (16/52) on three or more AEDs. The concomitant AEDs used were levetiracetam (n = 23), lamotrigine (n = 13), valproate (n = 5), topiramate (n = 4) and 13 further AEDs (n = 25).

Conclusions: The majority of women received lacosamide as part of an antiepileptic polytherapy including known teratogens, making assessment of the drug's prenatal toxicity difficult. However, available data do not support the assumption of lacosamide being a major teratogen.

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#35 Paternal exposure to immunosuppressive drugs: possible influence on pregnancy outcome and infant's health, a systematic review

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Introduction: Although there are theoretical concerns about the possible influence on fertility, pregnancy outcome or complications and health of the offspring, preconceptional paternal drug exposure has not been studied significantly. This applies to immunosuppressive drugs like methotrexate and mycophenolic

acid. As start of a research project on paternal immunosuppressive drugs and/or autoimmune diseases and their possible influence on fertility, pregnancy outcomes and child health we performed two systematic reviews, one on drugs and one on diseases. Here we give an overview of the pregnancy and infant outcomes of immunosuppressive drugs from the initial search.

Methods: The protocol for this systematic review is written according to the PRISMA-P statement and registered in PROSPERO. A systematic literature search was performed in Embase and MEDLINE. Additional sources included Cochrane Central register of Controlled Trials, Web of Science and Google Scholar. The initial search was done in April 2018. For each database a search profile was developed including keywords regarding male fertility, paternal exposure, pregnancy outcomes and complications and infant's health. This was combined with immunosuppressive drugs. The literature search was limited to the English language and human subjects. The following type of studies were included: case control studies, cohort studies, cross-sectional studies, case reports and case series. The methodological quality of the studies was assessed with the Newcastle Ottawa Scale.

Results: After deduplication 3720 publications were eligible for title and abstract screening. Full text reading was done for 260 publications, which resulted in inclusion of 41 references on pregnancy and infant related outcomes. Since 2016, 7 population-based cohort studies were published based on the Danish registries, with potential overlap in included pregnancies. The Norwegian registries were used in 2 population-based cohort studies. Other cohort studies used data from Teratology Information Services, the USA National Transplant Pregnancy Registry or hospitals. Case series were mostly based on hospital records. Most studies looked at azathioprine and/or 6-mercaptopurine (n = 8) or methotrexate (n = 5). Other drugs in studies were TNA-alpha blockers, calcineurin inhibitors, mycophenolic acid or colchicine. The most frequently reported outcomes were pregnancy outcome (e.g. miscarriage, live birth), preterm birth (gestational age), low birthweight (birth weight) and congenital abnormalities, in general no major differences between exposed and the comparison group were reported.

Conclusions: Paternal use of immunosuppressive drugs preconceptionally has received more attention in the last years. Preliminary data of the systematic review implies that the reported outcomes after immunosuppressive drug use do not differ significantly from the comparison group. The numbers in the different publications, and also the total number of pregnancies included, are still low. The quality of the publications ranges between high and low.

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#36 Gadolinium-based contrast agents in pregnant women

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Introduction: Gadolinium-based contrast agents are commonly used for magnetic resonance imaging. Iodinated contrast media can be classified as either ionic or non-ionic and high-osmolar or low-osmolar. Iohexol which is one of iodinated non-ionic, low-osmolar contrast medium is used for visualization during angiography and