

## Publication

A review of the evidence on the risk of congenital malformations and neurodevelopmental disorders in association with antiseizure medications during pregnancy

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Introduction: The majority of women with epilepsy require treatment with antiseizure medications (ASM) throughout pregnancy. However, in utero exposure to several ASM has been associated with an increased risk of congenital malformations and/or neurodevelopmental disorders (CM/NDD) in the child, but observational evidence is methodologically heterogeneous. Areas covered: We critically evaluate current evidence on the risk of CM/NDD in children of women with epilepsy after in utero exposure to different ASM. We highlight characteristics of different data sources and discuss their benefits and drawbacks. This review includes evidence published before December 2020. Expert opinion: Given the lack of randomized controlled trials, evidence on in utero safety of ASM originates from methodologically heterogeneous post-marketing observational studies based on registries, prospective cohorts, and large electronic health databases. It has been clearly demonstrated that valproate is associated with a high risk of CM/NDD, whereas lamotrigine and levetiracetam are relatively safe. However, evidence is less explicit for other ASM. Reported risks vary depending on the size and origin of the underlying study population, the definition of exposure and outcomes, and other aspects of the study design. Increased collaboration between data sources to increase sample size is desirable.

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