

Prenatal use of newer antiepileptic drugs not associated with increased risk of major birth defects

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Use of newer-generation antiepileptic drugs, which are also prescribed for bipolar mood disorders and migraine headaches, during the first trimester of pregnancy was not associated with an increased risk of major birth defects in the first year of life among infants in Denmark, according to a study in the May 18 issue of *JAMA*. Older-generation antiepileptic drugs are associated with an increased risk of birth defects.

"Epilepsy during [pregnancy](#) is a therapeutic challenge. Since the 1990s, the number of licensed antiepileptic drugs has substantially increased, but safety data on first-trimester use of newer-generation antiepileptic drugs and birth defects are limited," according to background information in the article.

Ditte Molgaard-Nielsen, M.Sc., and Anders Hviid, M.Sc., Dr.Med.Sci., of the Statens Serum Institut, Copenhagen, Denmark, conducted a study to analyze the association between the use of lamotrigine, oxcarbazepine, topiramate, gabapentin, and levetiracetam (newer-generation antiepileptic drugs) during the first trimester of pregnancy and the risk of any major birth defects. The study included data on 837,795 live-born infants in Denmark from January 1996 through September 2008. Individual-level information on dispensed antiepileptic drugs to mothers, birth defect diagnoses, and potential confounders (factors that can influence outcomes) were ascertained from nationwide health registries.

Among the [live births](#) included in the study (837,795), 19,960 were diagnosed with a major birth defect (2.4 percent) during the first year of life. Among 1,532 pregnancies exposed to lamotrigine, oxcarbazepine, topiramate, gabapentin, or levetiracetam at any time during the first trimester, 49 infants were diagnosed with a major [birth defect](#)

(3.2 percent) compared with 19,911 infants (2.4 percent) among 836,263 unexposed pregnancies. After adjusting for various factors, the authors found that exposure to lamotrigine, oxcarbazepine, topiramate, gabapentin, or levetiracetam at any time during the first trimester was not associated with an increased risk of major birth defects. Gabapentin and levetiracetam exposure during the first trimester was uncommon.

The prevalence odds ratios for any major birth defects after exposure to any newer-generation antiepileptic drugs during the first trimester were not statistically different for mothers with epilepsy, mood affective disorder or migraine, or without a diagnosis.

"Our study, to our knowledge, is the largest analytic cohort study on this topic and provides comprehensive safety information on a class of drugs commonly used during pregnancy. The use of lamotrigine and oxcarbazepine during the first trimester was not associated with moderate or greater risks of major birth defects like the older-generation [antiepileptic drugs](#), but our study cannot exclude a minor excess in risk of major birth defects or risks of specific birth defects. Topiramate, [gabapentin](#), and levetiracetam do not appear to be major teratogens [an agent that can cause malformations in an embryo or fetus], but our study cannot exclude minor to moderate risks of major [birth defects](#)," the authors conclude.

More information: *JAMA*. 2011;305[19]1996-2002.

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