

Epilepsy drug may not increase risk of birth defects

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Babies born to pregnant women taking the epilepsy drug lamotrigine may not be at an increased risk of birth defects, such as cleft lip, cleft palate or clubfoot, according to a study published in the April 6, 2016, online issue of *Neurology*, the medical journal of the American Academy of Neurology.

Lamotrigine is an epilepsy drug used on its own or in combination with other medications to control seizures; it is also prescribed to prevent mood swings for those with bipolar disorder. Maintaining effective epilepsy treatment during pregnancy is important because seizures may cause harm to the fetus.

"An initial study of this drug showed an [increased risk](#) for [cleft lip](#) or cleft palate, but a number of other studies since have not, and a previous study showed an increased risk of [clubfoot](#)," said study author Helen Dolk, PhD, of Ulster University in Northern Ireland, United Kingdom. "This particular study had a much larger population size?more than double the size of the previous study."

For the study, researchers looked at data on more than 10 million births during a span of 16 years. Of those, there were 226,806 [babies](#) with [birth defects](#). Within that group, researchers found 147 babies who were exposed to the drug lamotrigine within the first trimester of pregnancy and who had non-genetic birth defects. Researchers found that babies with cleft lip, cleft palate or clubfoot were not significantly more likely than babies with other birth defects to have been exposed to lamotrigine

in the first trimester.

In the general population, one in every 700 babies is born with cleft lip or cleft palate, or 0.14 percent. Nearly one in 1,000 babies is born with clubfoot.

"We cannot exclude a small risk, but we estimate the excess risk of cleft lip or cleft palate among babies exposed to the drug to be less than one in every 550 babies. Since excess risks of cleft lip or palate have been reported for a variety of antiepileptic drugs, we recommend that for all mothers with epilepsy, whatever their drug exposure, special attention be given to examining the baby for [cleft palate](#)," said Dolk. "We did not have specific information on lamotrigine dosage so additional study is recommended, especially of high doses."

Provided by American Academy of Neurology

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