

Efavirenz in HIV-positive pregnant women, risk of neurological condition in children

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Antiretroviral therapy (ART) is a vital treatment that helps prevent a pregnant woman from passing HIV to her baby, but one type of ART medication may increase the risk the child will develop a neurological condition, according to new research being presented at IDWeek 2018.

Researchers found children of women whose ART regimen included [efavirenz](#) were 60 percent more likely to develop a [neurological condition](#), such as microcephaly (small head), seizures (from a high fever or other cause) and eye abnormalities than children whose mothers took other ART medications. The findings are part of the SMARTT (Surveillance Monitoring for ART Toxicities) study, which follows children to determine the long-term effects of specific ART medications taken during pregnancy.

"Antiretroviral therapy during pregnancy saves lives and reduces the risk of a fetus becoming infected to almost zero," said Claudia S. Crowell, MD, MPH, lead author of the study and assistant professor of pediatrics at the University of Washington and Seattle Children's Hospital. "Our ultimate goal is to determine which ART medications are safest for the baby and which should be avoided during pregnancy."

Previous research suggested that being exposed to efavirenz before birth does not increase the risk of defects and adverse outcomes at birth (such as neural tube defects and preterm birth). The new study is a long-term analysis that looks at neurological [conditions](#) diagnosed in infancy and childhood. Researchers evaluated 3,747 HIV-exposed uninfected

children enrolled in the SMARTT study, more than 95 percent of whom had been exposed to an ART regimen before birth. They found 237 were diagnosed with neurological conditions during childhood: the average age at which diagnoses were confirmed was two years old. Overall, 16 babies with neurological conditions were born to mothers who had taken ART containing efavirenz. When comparing regimens, researchers determined 9.6 percent of babies born to women on efavirenz had a neurological condition compared to 6.2 percent of babies born to women on ART regimens that did not contain efavirenz. After considering other risk factors the former were 60 percent more likely to be diagnosed with a neurological condition. Researchers also found a suggested association between the use of dolutegravir (another ART medication) during pregnancy and long-term neurological conditions, but only 94 children had been exposed to that [medication](#) and 4 developed neurological conditions, Dr. Crowell said.

There are a variety of ART regimens, which typically include a combination of medications. Without ART, the risk of HIV passing from mother to unborn child is about one in four. Experts estimate ART during pregnancy has prevented about 1.6 million [babies](#) from being infected since it became the standard of care more than 20 years ago.

Due to side effects and because there are more effective alternative regimens, efavirenz is not the recommended as part of the first-line therapy for women in the United States, whether pregnant or not. U.S. guidelines recommend atazanavir-, darunavir- or raltegravir-based regimens for pregnant women, but suggest women who are already taking efavirenz when they become pregnant remain on the regimen if it has been effectively controlling their infection and they have been tolerating it well. Guidelines do recommend that [women](#) be switched from some ART medications (such as d4T and ddI), but efavirenz is not one of them.

"Our research suggests the long-term neurological effects of efavirenz on these [children](#) need to be studied further," said Dr. Crowell.

Provided by Infectious Diseases Society of America

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