What happens when women stop MS treatment during pregnancy?

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Two new studies look at the effects of stopping the newer, stronger drug natalizumab for multiple sclerosis (MS) during pregnancy. Natalizumab is generally prescribed for people with MS who have not responded to or cannot tolerate other treatments for MS as it can have a rare but potentially fatal side effect.

The researchers found that women who take natalizumab for MS may experience increased disease activity if they stop taking the drug prior to pregnancy, however the risk may be reduced if they take the drug up until conception, according to a study published the February 7, 2018, online issue of *Neurology*, the medical journal of the American Academy of Neurology. The second, related study says taking natalizumab during the first trimester may increase the risk of miscarriage, but the risk is small and within the risk range of miscarriage in the general population.

Earlier studies have shown that MS is not associated with a greater risk of birth defects and pregnancy has no long-term effects on the disease process, and older medications, interferon betas, have been shown to be generally safe to take during pregnancy. But little research has been done on the effects of natalizumab. Studies in people who were not pregnant have shown that disease activity can increase severely after people stop taking the drug.

"Pregnancy planning can be difficult when a woman has MS because she and her physician must weigh the risks versus the benefits of

medications that control MS disease activity," said study author Emilio Portaccio, MD, of the Don Carlo Gnocchi Foundation in Florence, Italy. "We chose to conduct two studies to investigate the risks of natalizumab to mother and child so that women, with the help of their physicians, may make more informed decisions about pregnancy."

For both studies, researchers tracked 92 pregnancies in 83 women taking natalizumab for relapsing-remitting MS. They were divided into two groups, those who stopped taking natalizumab before their last menstrual period and those who stopped taking the drug after their last period. In all, 75 percent of the pregnancies were exposed to natalizumab for an average of just over a week. Researchers followed up with the women every six months, as well as when they had a relapse and one year after birth. There were 75 live births among the 92 pregnancies.

For the study on the risks to mothers, disease activity in the 92 pregnancies was compared to disease activity in 350 pregnancies in women with MS who either took no medication or who took interferon betas.

Among the pregnancies that were exposed to natalizumab, the relapse rate during pregnancy was three times higher, with more disease activity seen in the first trimester and after giving birth when compared to pregnancies in women who took interferon betas or no drug for MS. During pregnancy, 37 percent of the women taking natalizumab had at least one relapse, compared to 10 percent of the other women. Disease progression occurred in 16 percent of the women taking natalizumab and was reduced in those for whom medication was reintroduced earlier.

For the study on risks to babies, researchers found that for pregnancies exposed to natalizumab in the first trimester, the risk of miscarriage was four times higher than pregnancies where a mother took interferon betas or nothing for MS. However, that rate of 17 percent for natalizumab-

exposed pregnancies was close to the rate for the general population, which was 14 percent.

While researchers also looked at risk of birth defects, the results were not conclusive, and more research needs to be done in a larger group of pregnancies.

Portaccio said, "Our findings suggest that if women who take natalizumab for MS want to become pregnant, it may be best to continue treatment up until a pregnancy test is positive and then at that point discontinue use," said Portaccio. "While there is still a risk of increased disease activity, this course of action may lower that risk."

Limitations of these studies include that women treated with natalizumab may differ from women not treated with that drug in ways that were not measured by the study and that relapse severity was not measured.

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