



## Birth Outcomes in Pregnant Women Taking Fluoxetine

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### ABSTRACT

*Background* Although fluoxetine is the most frequently prescribed antidepressant drug in the United States, its safety in pregnant women has not been established.

*Methods* From 1989 through 1995, we prospectively identified 228 pregnant women taking fluoxetine. We compared the outcomes of their pregnancies with those of 254 women identified in a similar manner who were not taking fluoxetine.

*Results* The rate of spontaneous pregnancy loss did not differ significantly between the women treated with fluoxetine and the control women (10.5 percent and 9.1 percent, respectively), nor was the rate of major structural anomalies significantly different (5.5 percent vs. 4.0 percent). Among the 97 infants exposed to fluoxetine who were evaluated for minor anomalies, the incidence of three or more minor anomalies was significantly higher than among 153 similarly examined control infants (15.5 percent vs. 6.5 percent,  $P = 0.03$ ). As compared with the 101 infants exposed to fluoxetine only during the first and second trimesters, the 73 infants exposed during the third trimester had higher rates of premature delivery (relative risk, 4.8; 95 percent confidence interval, 1.1 to 20.8), admission to special-care nurseries (relative risk, 2.6; 95 percent confidence interval, 1.1 to 6.9), and poor neonatal adaptation, including respiratory difficulty, cyanosis on feeding, and jitteriness (relative risk, 8.7; 95 percent confidence

interval, 2.9 to 26.6). Birth weight was also lower and birth length shorter in infants exposed to fluoxetine late in gestation.

*Conclusions* Women who take fluoxetine during pregnancy do not have an increased risk of spontaneous pregnancy loss or major fetal anomalies, but women who take fluoxetine in the third trimester are at increased risk for perinatal complications.

## **Source Information**

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