

Antidepressant drug linked with increased risk of birth defects when taken in early pregnancy

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Using paroxetine—a medication prescribed to treat conditions including depression, obsessive-compulsive disorder, anxiety and posttraumatic stress disorder—during the first trimester of pregnancy may increase newborns' risk of congenital malformations and cardiac malformations. That's the conclusion of a recent analysis published in the *British Journal of Clinical Pharmacology*.

Up to one-fifth of women of childbearing age experience [depressive symptoms](#) that often lead to mild to moderate depression, and prescriptions for antidepressants during pregnancy have increased in recent years. The most common drugs for treating depression in

pregnant women are selective serotonin reuptake inhibitors, and up until 2005, one drug in that class—paroxetine—was considered to be safe for use during pregnancy. A small unpublished study conducted by the manufacturer, however, suggested an [increased risk](#) of cardiac malformations in infants exposed to paroxetine before birth. Subsequent studies using various study designs in different populations across Europe and North America generated conflicting results in terms of statistical significance, although a trend remained towards an increased risk.

To provide a comprehensive assessment of the effects of paroxetine on newborns, a team led by Professor Anick Bérard, PhD, of CHU Sainte-Justine and the University of Montreal, conducted a literature review and meta-analysis of all relevant studies published from 1966 to 2015. The investigators uncovered 23 eligible studies.

Compared with no use of paroxetine, first trimester use of paroxetine was associated with a 23 percent increased risk of any major [congenital malformations](#) and a 28 percent increased risk of major cardiac malformations in newborns. The investigators noted that the baseline risk of major malformations is 3 percent and of cardiac malformations is 1 percent; however, any increase in risk is significant, especially when considering that the benefit of using selective serotonin reuptake inhibitors during pregnancy—when changes in metabolism cause the drugs to be cleared from the body at a faster rate—is debatable.

"Given that the benefits of antidepressants overall, and selective serotonin reuptake inhibitors including paroxetine specifically, during pregnancy is questionable at best, any increase in risk—small or large—is too high," said Dr. Bérard. "Indeed, the risk/benefit ratio suggests non-use in women with mild to moderately depressive symptoms, which is 85 percent of [pregnant women](#) with depressive symptoms. Therefore, planning of [pregnancy](#) is essential, and valid

treatment options such as psychotherapy or exercise regimens are warranted in this special population."

More information: Anick Bérard et al. The risk of major cardiac malformations associated with paroxetine use during the first trimester of pregnancy: A systematic review and meta-analysis, *British Journal of Clinical Pharmacology* (2015). [DOI: 10.1111/bcp.12849](https://doi.org/10.1111/bcp.12849)

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