Taking Vedolizumab in Pregnancy Did Not Increase the Risk of Birth Defects or Adverse Pregnancy Outcomes

LA JOLLA, CA – Vedolizumab (sold under the trade name Entyvio®) is a medication that is used to treat Crohn's disease and ulcerative colitis, which are two forms of inflammatory bowel disease (IBD). For women who became pregnant while taking vedolizumab, there are limited data on whether this medication could affect the pregnancy and the developing baby. Our study sought to examine this question by evaluating the safety/risk of vedolizumab use in pregnant women who were participating in MotherToBaby Pregnancy Studies.

What did we study? From 2015 to 2022, we enrolled 275 pregnant women in the United States and Canada; 99 of the women had IBD and reported taking vedolizumab sometime during their pregnancy, 76 women had IBD but were being treated with other biologic medications, and the remaining 100 women did not have IBD and were not exposed to vedolizumab or other biologic medications.

We interviewed the mothers up to three times during their pregnancy and once at the end of their pregnancies. We also collected information from the medical records of both mom and baby. Finally, a subset of the babies was examined by one of our study doctors. We then compared the three groups of women by looking at several pregnancy and birth outcomes, including pregnancy loss, preterm birth, and birth defects.

What did we find? We found no meaningful differences in the rates of pregnancy loss, preterm birth, or birth defects between the groups. There were also no meaningful differences between the groups on infant growth measures at birth and at 1 year of age.

What's the takeaway? Taking vedolizumab in pregnancy did not increase the chance of birth defects or other adverse pregnancy outcomes. Our study provides additional reassuring evidence for women with IBD who take vedolizumab during pregnancy.

Reference:

Chambers CD, Johnson DL, Luo Y, Xu R, Adam MP, Braddock SR, Jones KL; OTIS Collaborative Research Group. Birth Outcomes in Women Who Have Taken Vedolizumab in Pregnancy: Results from the Vedolizumab Pregnancy Exposure Registry. Am J Gastroenterol. 2025 Jun 11. doi: 10.14309/ajg.0000000000003593. Epub ahead of print. PMID: 40498121.

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Asthma is a common medical condition affecting women of reproductive age, yet many of the medications used to treat it are not well-studied for their safety in pregnancy and lactation, leading many asthma sufferers to discontinue their medications when they are expecting or nursing. Since uncontrolled asthma can lead to poor outcomes for both mom and baby, national experts led by Dr. Christina Chambers, one of our MotherToBaby specialists based at the University of California San Diego and an investigator for the Vaccines and Medications in Pregnancy Surveillance System (VAMPSS), have come together to detail an action plan for filling the information gaps about asthma medication safety in pregnancy and lactation.

Published online this week in ***The Journal of Allergy and Clinical Immunology***, the action plan describes the proceedings from a workshop conducted in November 2019 and supported by the National Heart, Lung, and Blood Institute and the Office of Research on Women's Health in the Office of the Director of the National Institutes of Health and the U.S. Food and Drug Administration Office of Women's Health. The workshop assembled key stakeholders who were tasked with prioritizing, strategizing and mobilizing action steps on gaps in knowledge regarding asthma medication safety in pregnancy and lactation. The overarching goal of the workshop was to identify approaches that could be applied broadly to fill gaps in data about the safety of all medications and vaccines in pregnancy and lactation.

As a result of the workshop, a multi-stakeholder consortium on asthma medications in pregnancy and lactation has been developed. In order to address the evidence gaps and aid in populating medication labels with data that health providers can use to inform clinical decision making, the consortium developed a plan to systematically obtain necessary data in the most efficient and timely manner. The consortium also recommended the development of guidelines for the evaluation and management of asthma during pregnancy and lactation that adhere to the standards developed by the National Academy of Medicine, which would not only offer recommendations for patients, caregivers, and health providers at the point-of-care but also highlight specific evidence gaps that warrant further research. According to Chambers, "the need for high quality information regarding medication and vaccine safety in pregnancy and lactation is great – implementation of the recommendations stemming from this workshop will be a major step forward in addressing this health disparity."

In partnership with VAMPSS, MotherToBaby conducts observational pregnancy studies to evaluate the safety of medications used to treat asthma and other health conditions. MotherToBaby Pregnancy Studies accept both healthcare provider referrals as well as patient self-referrals. To learn more, visit: MotherToBaby.org/Studies.

Read the Abstract

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Taking Vedolizumab in Pregnancy Did Not Increase the Risk of Birth Defects or Adverse Pregnancy Outcomes

602 Pregnancies Examined by the Non-Profit Organization of Teratology Information Specialists

LA JOLLA, CA –A new study conducted by birth defects experts from the Organization of Teratology Information Specialists (OTIS) suggests adalimumab use in pregnancy was not associated with an increased risk for adverse outcomes examined, such as major structural birth defects, spontaneous abortion and preterm delivery. The findings were published today in the Public Library of Science (PLOS) One Journal.

The prospective research study conducted by OTIS examined 602 pregnancies that occurred between 2004 – 2016 in women across the U.S. and Canada. Researchers enrolled pregnant women into the observational cohort study who had or had not taken adalimumab for their autoimmune disease, as well as generally healthy pregnant women for comparison. OTIS is the scientific non-profit society that provides the no-cost MotherToBaby information service and enrolls women through the MotherToBaby Pregnancy Studies Research Center at the University of California San Diego. Financial support for the adalimumab study was provided by AbbVie.

“Many women hoping to start a family rely on adalimumab to control symptoms related to crippling autoimmune diseases such as rheumatoid arthritis or Crohn’s Disease,” said lead study author Christina Chambers, PhD, MPH, OTIS/MotherToBaby president and professor of pediatrics at the University of California, San Diego. “The fact that this study showed no increased risk in adverse birth outcomes with the use of adalimumab in pregnancy is important since not a lot of research was previously available on this particular medication.”

The study also found that regardless of whether they took adalimumab or not, pregnant women with rheumatoid arthritis or Crohn's Disease were at an increased risk of preterm birth (delivery before 37 weeks of pregnancy).

"Studies on medication use in general are lacking when it comes to understanding their effects on pregnancy, making it difficult for pregnant women and their healthcare providers to make informed decisions," said Dr. Chambers. "We are proud to add valuable information to the literature and encourage more pregnant women to consider volunteering for critical observational studies."

For more information on all of the current MotherToBaby Pregnancy Studies, please visit https://mothertobaby.org/pregnancy-studies/.

More about OTIS and MotherToBaby

The Organization of Teratology Information Specialists (OTIS) is a professional scientific society made up of individuals engaged in assessing and evaluating risks to pregnancy and breastfeeding from environmental exposures. Members include, but are not limited to, specialists in the fields of: obstetrics and gynecology, pediatrics, genetics, dysmorphology, perinatal epidemiology, teratology, behavioral teratology, pharmacy, genetic counseling, nursing, midwifery, maternal and child health, public health, and includes experts that provide MotherToBaby services and researchers that conduct MotherToBaby Pregnancy Studies. MotherToBaby is a suggested resource by many federal agencies including the Centers for Disease Control and Prevention (CDC). To learn more about ongoing MotherToBaby Pregnancy Studies, call (877) 311-8972, email MotherToBaby@ucsd.edu or visit www.MotherToBaby.org.

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