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

The Bilingual Website is the Latest Addition to the Non-Profit's Toolkit to Promote Healthy Pregnancies and Reduce Birth Defects

BRENTWOOD, TN – ¿Hablas español? ¡Sí! In time for January's Birth Defects Awareness Month, MotherToBaby is proud to announce the launch of its fully bilingual (English/Spanish) website. It's the first of its kind for housing an extensive bilingual library of fact sheets on everything from alcohol to zolpidem during pregnancy and breastfeeding as well as connecting bilingual experts with parents and healthcare providers.

Only select portion of MotherToBaby's resources were previously available in Spanish. The now fully bilingual website is designed to fill the gap in the disparities of health education information for pregnant and breastfeeding individuals who are Spanish-speakers. MotherToBaby wants to improve birth outcomes in the Latinx community by giving improved access to language-appropriate resources to families and health professionals.

"It's our experience that all parents and parents-to-be want the best information possible in order to have a healthy baby," said Lorrie Harris-Sagaribay, MPH, a bilingual teratogen information specialist and the MotherToBaby President-Elect. "No matter what the language they speak is, we want everyone to have access to the best, expert health information possible. Making our free resources available in the second most-used language in the U.S. will help us reach many who are currently underserved."

MotherToBaby, a no-cost service of the international non-profit Organization of Teratology Information Specialists (OTIS), has been available to the public for more than 30 years. During that time, it has become the leader in birth defects research as well as answering questions the public has about exposures, like medications, vaccines, beauty products, herbal supplements, workplace exposures and much more, during pregnancy and breastfeeding. MotherToBaby is a suggested resource by many federal agencies including the Centers for Disease Control and Prevention (CDC).

The fully bilingual website comes on the heels of other Spanish resources previously available including more than 300 fact sheets, a phone information service (866-626-6847), texting line (855-999-3525), and live chat and email

(available on MotherToBaby.org). Just some of the website updates include one-stop resource hubs organized by exposure topic and health field, a FREE online materials ordering system for patient education and materials, and fully translated information about the research arm of the organization, MotherToBaby Pregnancy Studies. Much of the information that the scientific community knows about medication and vaccine use during pregnancy comes from observational studies. With accessible information about study participation in Spanish, MotherToBaby is aiming to increase participant diversity and better reflect the community that may need to take these drugs to treat or prevent illness.

“The risk to the developing baby from certain exposures during a pregnancy can vary greatly depending on timing of the exposure and much more,” said Harris-Sagaribay. “To be able to provide information tailored to a pregnant person’s personal circumstance allows for better informed decision-making. I’m proud to be part of a service that empowers parents like that not only in English but also in Spanish.”

The Spanish-language website is just one of MotherToBaby’s latest effort in making health education information more accessible to people outside of native English speakers. MotherToBaby is exploring the expansion of its bilingual resources to make them available in more languages. For example, it recently made its COVID-19 mRNA Vaccines fact sheet available in Arabic, Chinese, Portuguese, Tagalog and Vietnamese.

Visit the new Spanish-language website at MotherToBaby.org/es. The MotherToBaby website is not intended to be a substitute for professional judgment. Users should consult personal healthcare providers for pregnancy and breastfeeding advice related to their particular situation.

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.

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Join MotherToBaby and partner organizations around the world for a special World Birth Defects Day Facebook and Instagram Live Chat March 3 at 10a PT/1p ET.

How to participate: Follow @MotherToBaby on Facebook or @mothertobabyotis on Instagram (or both). You might get a notification from Facebook or Instagram that the MotherToBaby page you follow is going live at the live broadcast start time. Alternatively, just go to MotherToBaby's profile on either Facebook or Instagram at the broadcast start time (10a PT/1p ET). You can also get a reminder for the live event by clicking "going" on the Facebook event created for it: https://www.facebook.com/events/213655426471361/

On Facebook, the live video should just be playing at the top of MotherToBaby's page. On Instagram, you will see a small badge around the story circles at the top of the screen that says "live." Tap to enter the live stream. The person streaming will know that you are tuning in.

With either platform, once you are watching the live stream, you can comment or ask questions, the same way you'd engage with a non-live post. MotherToBaby's president, Christina Chambers, PhD will be joined by Drs. Kenneth Lyons Jones, MD and Miguel Del Campo, MD to answer questions in English and Spanish about birth defects.

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PLEASE NOTE: This webinar has already passed, but the recorded version can be seen at the following link: http://bit.ly/2Hfcr6z

OTIS, Teratology Society, SMFM, NSGC Team Up to Shed Light on Prenatal and Postnatal Marijuana Exposure Effects

BRENTWOOD, TN – From plant form to CBD oil, with increasing legalization of marijuana across U.S. states, there comes the need for more information on its impact should a consumer become pregnant. Birth defects experts from the Organization of Teratology Information Specialists (OTIS), the scientific non-profit society that provides the MotherToBaby no-cost service, are offering the latest data surrounding marijuana exposure in pregnancy and lactation during a free webinar for healthcare providers on May 2, 2019 at 12p Pacific/3p Eastern.

"If I use edibles instead of smoke marijuana, that should be safer during pregnancy and breastfeeding, right?" – It's just one of the many questions the MotherToBaby service, which answers questions about exposures during pregnancy and breastfeeding via phone, text, live chat and its MotherToBaby.org website, is now receiving on a regular basis according to Christina Chambers, PhD, MPH, MotherToBaby president and professor of pediatrics at the University of California, San Diego. Dr. Chambers also heads up Mommy's Milk Human Milk Research Biorepository, the first-ever research database of human breast milk which produced a ground-breaking study last year suggesting that marijuana can linger in breast milk for far longer (up to six days) than previously thought. "As more states legalize marijuana for medicinal and recreational use, it's critical we look at how it's impacting the next generation," she said.

The webinar, "Sifting through the Smoke: The Latest Research Surrounding Marijuana Exposure in Pregnancy and Breastfeeding," is a collaboration with the National Society of Genetic Counselors (NSGC) and, in addition to OTIS/MotherToBaby, will include presenters representing the Teratology Society and the Society for Maternal-Fetal Medicine (SMFM). The webinar is free and aimed at healthcare providers and researchers; registration is required at the following link: http://bit.ly/MarijuanaWebinar2019.

"Older studies have suggested that if a mother uses marijuana during pregnancy, she might be at risk for having a smaller baby born early and/or having it experience developmental delays," said Sarah Obican, MD, a Maternal-Fetal Medicine subspecialist at the University of South Florida, director of MotherToBaby's Florida affiliate, and Dr. Chambers' co-presenter for the webinar. "However, marijuana is produced today at a higher potency level, so it's critical we stay vigilant in our research to better understand its impact," she added.

The webinar is expected to run approximately one hour and presenters will be available to answer questions from attendees.

More about OTIS and MotherToBaby

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agencies including the Centers for Disease Control and Prevention (CDC). To be connected with a MotherToBaby expert, please call (866) 626-6847, text questions to (855) 999-3525 (standard messaging rates might apply, check with your carrier) or visit www.MotherToBaby.org.

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In case you missed it during January's Birth Defects Prevention Month, MotherToBaby, in coordination with the Society for Maternal-Fetal Medicine (SMFM) and the Teratology Society, offered a free two-part webinar series for healthcare providers on the importance of pregnancy exposure research, its challenges and the new Task Force on Research Specific to Pregnant and Lactating Women (PRGLAC) report. The recorded webinar series can be viewed at the following links:

• Current and Future Trends in Research with Pregnant and Lactating Women (Part 1): http://bit.ly/PregResearch1
• Using Registries and Crowdsourcing to Conduct Research with Pregnant and Lactating Women (Part 2): http://bit.ly/PregResearch2

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