Heartburn drugs deemed safe for fetuses: research

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H2 Blocker drugs, such as Famotidine, Cimetidine and Ranitidine, approved in the U.S. for acid reflux (heartburn), pose no significant risks for the fetus according to a large collaborative cohort study by researchers at Ben-Gurion University of the Negev.

The study published in the Journal of Clinical Pharmacology provides significant reassurance for the safety of the fetus when H2 blocker drugs are given to women to relieve acid reflux during pregnancy.

H2 blockers are among the most frequently recommended drugs for acid reflux symptoms of heartburn, regurgitation and trouble swallowing, which are common in pregnant women. The findings of a large cohort study examining infants born to mothers who were exposed to H2 blockers, particularly Famotidine, during pregnancy.

Usually symptoms of acid reflux are more frequent and more severe in the latter months of gestation. It has been estimated that between 30 percent to 80 percent of pregnant women are affected.

The study was a collaboration between Ben-Gurion University of the Negev, Soroka University Medical Center and Clalit Health Services -- all in Beer-Sheva, Israel -- along with the Division of Pharmacology, Hospital for Sick Children in Toronto, Canada. It was part of the doctoral thesis of Ilan Matok under the supervision of principal investigators epidemiologist Dr. Amalia Levy and pediatrician and clinical pharmacologist professor emeritus Rafael Gorodischer. The

study was conducted by the three Israeli entities as part of the BeMORE collaboration (Ben-Gurion MotheRisk Obstetric Registry of Exposure). The investigation of the safety of other medications commonly used off-label in pregnancy is an ongoing project of BeMORE investigators in large cohorts of women in Southern Israel.

"Of the vast majority of medications approved for use, there is insufficient data from human studies to determine whether the benefits of therapy exceed the risk to the fetus," according to the pediatrician and clinical pharmacologist, principal investigator Dr. Rafael Gorodischer, professor emeritus at Ben-Gurion University of the Negev. "Medicines are approved for use only after there is sufficient scientific evidence demonstrating the drug safety and effectiveness for its intended uses."

The safety of H2 blockers used during the first trimester of pregnancy was investigated by linking a database of medications dispensed over 10 years to all women registered in Clalit Health Services in the Southern District of Israel, with databases containing maternal and infant hospital records, and with therapeutic abortion records of Soroka University Medical Center, during the same period. In the study, 1,148 (or 1.4 percent) were exposed to H2 blockers during the first trimester of pregnancy of the 84,823 infants born to mothers during the study period.

The rate of major congenital malformations identified in the group that was exposed to H2 blockers during the first trimester was 5.7 percent (65 of 1,148 infants), as compared with a rate of 5.3 percent (4,400 of 83,675 infants) in the unexposed group.

According to principal investigator epidemiologist Dr. Amalia Levy of the BGU Faculty of Health Sciences, and chairwoman of the BeMORE collaboration, "Exposure to H2 blockers among this group was not associated with significantly increased risks of major congenital malformations. The results were unchanged when therapeutic abortions

of exposed fetuses were included in the analysis. Also, infants exposed in utero had no increased risk of perinatal mortality, low birth weight or premature birth".

More information: Journal of Clinical Pharmacology: "The Safety of H2Blockers Use During Pregnancy", J Clin Pharm OnlineFirst, doi:10.1177/0091270009350483

Source: American Associates, Ben-Gurion University of the Negev (news : web)