



Use of proton-pump inhibitors in early pregnancy and the risk of birth defects.

<https://arctichealth.org/en/permalink/ahliterature139078>

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Source: N Engl J Med. 2010 Nov 25;363(22):2114-23

Date: Nov-25-2010

Language: English

Publication Type: Article

Keywords: Adolescent
Adult
Cohort Studies
Congenital Abnormalities - epidemiology - etiology
Denmark - epidemiology
Female
Gastroesophageal Reflux - drug therapy
Humans
Live Birth
Middle Aged
Pregnancy
Pregnancy Complications - drug therapy
Pregnancy Trimester, First
Prevalence
Proton Pump Inhibitors - adverse effects - therapeutic use
Registries
Risk
Young Adult

Abstract: Symptoms of gastroesophageal reflux are common in pregnancy, but there are limited data on the risk of birth defects associated with exposure to proton-pump inhibitors (PPIs) in early pregnancy.

We conducted a cohort study to assess the association between exposure to PPIs during pregnancy and the risk of major birth defects among all infants born alive in Denmark between January 1996 and September 2008. We linked data from nationwide registries, including individual-level information on exposure to PPIs (prescriptions), birth defects, and potential confounders. Major birth defects, diagnosed within the first year of life, were categorized according to the standardized classification scheme of the European surveillance of congenital anomalies (EUROCAT). Our primary analyses assessed the use of PPIs from 4 weeks before conception through 12 weeks of gestation and from 0 through 12 weeks of gestation (first trimester).

Among 840,968 live births, 5082 involved exposure to PPIs between 4 weeks before conception and the end of the first trimester of pregnancy. There were 174 major birth defects in infants whose mothers had been exposed to PPIs during this period (3.4%), as compared with 21,811 in the group whose mothers had not been exposed (2.6%) (adjusted prevalence odds ratio, 1.23; 95% confidence interval [CI], 1.05 to 1.44). In analyses limited to exposure during the first trimester, there were 118 major birth defects among 3651 infants exposed to PPIs (3.2%), and the adjusted prevalence odds ratio was 1.10 (95% CI, 0.91 to 1.34). The risk of birth defects was not significantly increased in secondary analyses of exposure to individual PPIs during the first trimester or in analyses limited to the offspring of women who had filled PPI prescriptions and received enough doses to have a theoretical chance of first-trimester exposure.

In this large cohort, exposure to PPIs during the first trimester of pregnancy was not associated with a significantly increased risk of major birth defects. (Funded by the Danish Medical Research Council and the Lundbeck Foundation.).

Notes: Comment In: Ann Intern Med. 2011 Jun 21;154(12):JC6-1121690589
Comment In: N Engl J Med. 2010 Nov 25;363(22):2161-321105800
Comment In: Gastroenterology. 2011 Jul;141(1):389-9121620838

PubMed ID: 21105793 [View in PubMed](#) 