

Ondansetron Use In Early Pregnancy And The Risk Of Congenital Malformations – A Register Based Nationwide Cohort Study

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Background: Ondansetron is an effective antiemetic for the treatment of hyperemesis gravidarum.

Recently a Danish study found no increased risk of major malformations overall in women exposed to ondansetron, but unpublished Swedish data suggest an increased risk of heart defects.

Objectives: Therefore we conducted a nationwide cohort study testing if use of ondansetron during the first trimester was associated with different subgroupings of malformations.

Methods: The study included all women giving birth in Denmark between 1997 and 2010. The Medical Birth Registry was used to identify all women giving birth and the National Hospital Register was used to identify all offspring with a record of congenital malformation. Prescription data was obtained from the National Prescription Register. All major malformations and subgroupings are according to the EUROCAT classification system.

Results: We identified 903207 births in the study period. 1368 women redeemed a prescription of ondansetron in the first trimester of which 61 (4.7%) had offspring with a congenital malformation compared to 32241 (3.5%) in the unexposed group. The adjusted odds ratio (OR) of having an offspring with a major malformation after exposure to ondansetron was 1.2 (CI95% 0.9-1.5). This was mainly caused by an increased prevalence of heart defects (adjusted OR=1.6 (CI95% 1.1-3.1). OR for septal defects was ASD: 2.1 (CI95% 1.3-3.6), VSD: 2.3 (CI95% 1.2-4.2) and AVSD: 4.8 (CI95% 1.5-15.1)

Conclusion: We found an increase in the prevalence of major congenital heart defects in children whose mothers redeemed a prescription of ondansetron in the first trimester of pregnancy.