

The Outcomes of Pregnancy in Women Exposed to the New Macrolides in the First Trimester A Prospective, Multicentre, Observational Study

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Abstract

Background: Macrolides are a group of commonly prescribed antibiotics. There is some doubt surrounding the use of the newer macrolides in pregnancy.

Objective: The present study aimed to compare outcomes of pregnancies exposed to the new macrolides clarithromycin, azithromycin and roxithromycin with non-teratogenic preparations.

Methods: In this prospective, multinational, multicentre, controlled, observational study, information was obtained either from pregnant women or their healthcare professionals who contacted their local teratogen information services in Italy, Israel, the Czech Republic, the Netherlands and Germany seeking information after exposure to macrolides. The comparison group included women or their healthcare professional who contacted these centres with questions regarding known non-teratogenic preparations. Information on obstetric and other background parameters was collected at enrollment; after delivery, subjects or their healthcare professionals were contacted to ascertain pregnancy outcome parameters and other exposures through the remainder of the pregnancy.

Results: A total of 608 women exposed to macrolides during pregnancy were enrolled; 511 of the exposures occurred during the first trimester. The comparison group comprised 773 women exposed to non-teratogenic preparations during the first trimester of pregnancy. No significant difference in the rate of major congenital malformations was found between the study group and the comparison group (3.4% vs 2.4%; $p = 0.36$; odds ratio (OR) 1.42; 95% CI 0.70, 2.88) or in the rate of cardiovascular malformations (1.6% vs 0.9%; $p = 0.265$; OR 1.91; 95% CI 0.63, 5.62). No significant differences were found between subgroups of macrolides in the rates of major congenital malformations or cardiac malformations, although for azithromycin this was of borderline significance.

Conclusions: This study, in agreement with earlier smaller studies, suggests that the new macrolides do not pose a significantly increased risk of major congenital malformations or cardiac malformations.

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