

DSEN ABSTRACT

Darunavir and congenital malformations

Summary

- The authors conducted a population-based cohort study to evaluate the risk of congenital malformations (MCM) in pregnant women exposed to antiretroviral therapy.

Key messages

- Our data suggests that the use of antiretroviral therapy during the first trimester was not associated with the risk of overall MCM but was associated with an increased risk of defects of the small intestine.

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What is the issue?

- With more HIV-positive women becoming pregnant on combination antiretroviral therapies, concerns have been raised over their possible teratogenic effects.

What was the aim of the study?

- To quantify the risk of major congenital malformations associated with gestational combination antiretroviral use.

How was the study conducted?

- Using data from the Quebec Pregnancy Cohort between 1998 and 2015, we included women covered by the provincial drug plan who had a singleton live birth. Antiretroviral exposures were considered alone or in combinations if occurring during the first trimester. MCM diagnosed in the first year of life were identified in the RAMQ and MedEcho databases. Crude and adjusted odds ratios (aOR) with 95% confidence intervals (95% CI) were calculated for overall MCM and for each organ-specific outcome separately using generalized estimating equations (GEE) models.

What did the study find?

- Adjusting for potential confounders including maternal HIV status, antiretroviral therapy use during the first trimester of pregnancy was not associated with the risk of MCM (aOR=0.59, 95%CI 0.33, 1.06).
- Antiretroviral combination use during the first trimester was associated with an increased risk of defects of the small intestine (aOR 10.32, 95%CI 2.85, 37.38).

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Link to publication [Bérard et al, 2017.](#)