Abstract 1658

Cumulative update on pregnancy outcomes after fingolimod treatment in patients with multiple sclerosis

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**Background**

Assessment of the impact of fingolimod exposure on pregnancy outcomes is essential for the management of multiple sclerosis in pregnant women or those planning to conceive.

**Objectives**

To report the prevalence of major congenital malformations (MCMs) in infants following fingolimod exposure before (up to 8 weeks before last menstrual period) or during pregnancy.

**Methods**

Cumulative pregnancy outcome data are reported from prospective cases in the **N**ovartis **S**afety **d**ata**b**ase (NSDB) and Multinational **G**ilenya® **P**regnancy Exposure **R**egistry (GPR, which comprises a subset of NSDB cases also). For data in the NSDB and GPR, prospective cases were those for which pregnancy outcome was unknown and condition of the fetus was not assessed through prenatal testing at the time of enrolment. For the NSDB, if prenatal testing was not performed and results were either normal/not known, cases were also considered prospective. The prevalence (95% confidence interval [CI]) of MCMs in live births was estimated.

**Results**

As of 28th February 2020, 1762 prospective cases of maternal fingolimod exposure during pregnancy were reported in the NSDB and 177 in the GPR. Of all pregnancies with a known outcome, live births were: 754 (70.9%) in NSDB and 130 (85.0%) in GPR. Estimated prevalence of MCMs among live births was 3.19% (95% CI: 2.05; 4.71) in the NSDB and 4.6% (95% CI: 1.7; 9.8) in the GPR. As per recent meta-analysis, MCM prevalence in untreated MS is estimated to be 4.2% (95% CI: 2.7; 6.1), which is in line with that reported in this study. As per European Registration of Congenital Anomalies and Twins (EUROCAT), MCM prevalence in general population is 2.6% (95% CI: 2.6; 2.6). No clear discernible pattern of specific malformation was observed in the GPR. In the NSDB, the estimate of the proportion of live births with major cardiovascular anomalies (1.33% [95% CI: 0.64; 2.43]) was larger than, but not significantly different from the corresponding EUROCAT prevalence estimate (0.69%). This may be attributable to the difference in data collection and processing methodologies between EUROCAT and the NSDB.

**Conclusions**

The overall prevalence estimates of MCMs among live births in the NSDB and GPR are similar to that from the untreated MS population. Although both prevalence estimates are higher than the EUROCAT general population

prevalence, it is within 95% CIs for both databases. The wide 95% CI in the GPR prevents firm conclusions regarding increased risk of MCMs in fingolimod exposed patients.

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