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1. ABSTRACT

Title

Non-interventional safety study to investigate pregnancy outcomes in female patients exposed to SC Peginterferon beta-1a and IM Interferon beta-1a reported in a German patient support program

Keywords

Interferon, peginterferon beta-1a, pregnancy, lactation, breastfeeding, child development, multiple sclerosis

Rationale and background

A label change became applicable for the class of interferon beta therapies in September 2019: If clinically needed, the use of interferon beta therapies may be considered during pregnancy. Interferon beta therapies can be used during breast-feeding.

Research question and objectives

Assessment of pregnancy outcomes of women and infant outcomes exposed to interferon beta therapies, including breast-feeding practices and MS disease activity prior to and during pregnancy as well as postpartum.

Study design

This non-interventional, voluntary PASS was designed as a retrospective single-center open-label survey.

Setting

All female patients treated with peginterferon beta-1a therapy or interferon beta-1a therapy who fulfill the inclusion criteria were eligible to participate in the study.

Subjects and study size, including dropouts

426 adult female patients diagnosed with RRMS or CIS who were exposed to either peginterferon beta-1a therapy or interferon beta-1a therapy before or during pregnancy and who were registered in the PSP of Biogen's MS Service Center.

Variables and data sources

The primary endpoint variable is outcome of pregnancy. A pregnancy form was completed upon patients' report of pregnancy, and data from births and infants was collected after the expected date of the pregnancy outcome. Additionally, a standardized questionnaire completed during a telephone interview was used to systematically collect pregnancy outcome data in MS patients who reported "live birth" outcomes.

Results

A total of 426 women reporting 542 pregnancies between 12/2001 and 7/2020 were enrolled. Only 14 pregnancies were reported after the September 2019 label change. Mean age ±standard deviation (SD) was 32.9±4.7 years (range 19-50). Interferon exposure was documented during 374 pregnancies. Treatment was paused or stopped during 57.7% of pregnancies, taken continuously before and during 8.7%, and started

during 2.6% of pregnancies (31% interferon stopped before pregnancy or exposure unknown). The outcome of 466 pregnancies (86.0%) was a live birth (78.2 without defect, 2.8% with defects, 5.0% born prematurely). Spontaneous abortion occurred in 10.3% (36.2% in the subgroup continuing interferon therapy during pregnancy), whereas pregnancy was terminated electively in 2.6%. Five babies (0.9%) were stillborn. Complications during pregnancy occurred in 110 cases (20.3%). A total of 162 women completed the questionnaire for 192 live births (53.1% male) within the prospective part of the study. Mean±SD Apgar score improved from 8.9±1.3 at 1 min to 9.8±0.5 at 10 min. Mothers restarted interferon therapy or switched to another MS therapy postpartum in 51.0% and 14.1% of cases, respectively. Relapses occurred during 16 pregnancies (8.3%), predominantly during the second trimester, and postpartum in 32.8% of cases. Up to 18 months postpartum, the number of relapses remained low. In total, 158 children (82.3%) were breastfed, 12.7% exclusively up to 6 months, 21.5% of them during their mother's interferon exposure. During lactation, the mothers of 138 children (87.3%) remained relapse-free as did the mothers of 102 children (64.6%) after the introduction of supplementary feeding.

Discussion

Overall, the prevalence of spontaneous abortions and congenital anomalies was within the range reported for the general population (Buss et al. 2006, Zilie et al. 2014, Congenital Malformations Registry, 2005). As most in the PSP registered pregnancies occurred before the label change, the majority of mothers paused interferon therapy during pregnancy and breastfeeding. The low number of relapses corroborates data indicating a reduced relapse risk during pregnancy. These real-world data from a PSP confirm German and Scandinavian registry data and support the label extension of interferon beta therapies.

Marketing authorization holder(s)

Biogen Netherlands B.V.

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