INFORM - Interferon-Beta Exposure in the 2nd and 3rd Trimester of Pregnancy - a Register-Based Drug Utilisation Study in Finland and Sweden

First published: 22/12/2020

Last updated: 29/11/2024

Study Ongoing

Administrative details

PURI

https://redirect.ema.europa.eu/resource/48665

EU PAS number

EUPAS38736

Study ID

48665

DARWIN EU® study

No

Study countries

☐ Finland

☐ Sweden

Study description

Observational data have suggested no increased risk of adverse pregnancy outcomes associated with exposure to interferon-beta (IFNB) before or during pregnancy.

After the emergence of these data, the European Medicines Agency approved a label change for IFNB in September 2019, stating that use of IFNB during pregnancy may be considered, if clinically needed.

However, limited data on pregnancies exposed in the 2nd and 3rd trimesters were observed.

INFORM is a non-interventional drug utilisation study (DUS) to determine late pregnancy exposure (i.e. during the 2nd and 3rd trimester) to IFNB in Finland and Sweden, which will inform whether the number of exposed pregnancies is adequate to conduct a cohort study on adverse pregnancy outcomes, with a focus on late pregnancy exposure.

The number of pregnancies will be initially reported three years after the revised label implementation (September 2019) and will include data on pregnancies from 1996 in Finland and from 2005 in Sweden up through 31 December 2022.

If the number of pregnancies is deemed adequate for conducting the cohort study on adverse pregnancy outcomes, this DUS will be finalised with the drug utilisation data accrued up through 31 December 2022. If the number of pregnancies until 31 December 2022 is deemed inadequate, this study may be continued and the primary and secondary objectives may be examined five years after the revised label implementation, including pregnancies until 31 December 2024.

Study status

Ongoing

Research institutions and networks

Institutions

IQVIA

United Kingdom

First published: 12/11/2021

Last updated: 22/04/2024

Institution | Non-Pharmaceutical company | ENCePP partner

Contact details

Study institution contact

Victoria Banks

Study contact

PAS_registrations@iqvia.com

Primary lead investigator

Victoria Banks

Primary lead investigator

Study timelines

Date when funding contract was signed
Planned: 25/10/2019

Actual: 25/10/2019

Study start date
Planned: 01/01/2024

Actual: 20/03/2024

Data analysis start date
Planned: 01/03/2024

Actual: 01/04/2024

Date of interim report, if expected
Planned: 31/10/2024

Date of final study report
Planned: 30/10/2026

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Bayer AG, Biogen Netherlands B.V., Merck Europe, B.V. Novartis Europharm Limited

Study protocol

INFORM Protocol_V2.1 03 November 2020_signed_redacted.pdf(4.58 MB)

Regulatory

Was the study required by a regulatory body?

Yes

Is the study required by a Risk Management Plan (RMP)?

EU RMP category 3 (required)

Methodological aspects

Study type

Study type list

Study topic:

Human medicinal product

Study type:

Non-interventional study

Scope of the study:

Drug utilisation

Main study objective:

To determine the number of pregnancies exposed to IFNB during late pregnancy, the 2nd and 3rd trimesters, in Finland and Sweden.
This informs whether the number of exposed pregnancies is adequate to conduct a cohort study on adverse pregnancy outcomes, with a focus on late pregnancy exposure.

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

Study drug International non-proprietary name (INN) or common name

INTERFERON BETA-1A

INTERFERON BETA-1B

Anatomical Therapeutic Chemical (ATC) code

(L03AB07) interferon beta-1a

interferon beta-1a

(L03AB08) interferon beta-1b

interferon beta-1b

(L03AB13) peginterferon beta-1a

peginterferon beta-1a

Medical condition to be studied

Multiple sclerosis

Population studied

Age groups

Adolescents (12 to < 18 years)

Adults (18 to < 46 years)

Adults (46 to < 65 years)

Special population of interest

Pregnant women

Estimated number of subjects

100

Study design details

Outcomes

1. The number of pregnancies of women with MS exposed to IFNB before and during pregnancy, not allowing exposure to other MS Disease Modifying Drugs (MSDMDs)
2. The level of precision for the risk of pre-defined adverse pregnancy outcomes in late pregnancy that can be obtained with the available number of pregnancies
3. The annual number of pregnancies of women with MS in the exposure groups:

a) The number of pregnancies of women with MS in Finland and Sweden allowing exposure to other MSDMDs

b) The annual number of women with MS of childbearing age, and with dispensed IFNB in 2015-2022

Data analysis plan

Analyses will be descriptive and exclusively categorical variables are included. The categorical variables will be summarised as numbers of women and pregnancies and as proportions of the relevant denominator.

The following will be reported:

1. The number of pregnancies by exposure status, without allowing exposure to other MS Disease Modifying Drugs (MSDMDs) than IFNB, by calendar year of last menstrual period (LMP) and during the study period.

2. The number of pregnancies in the late pregnancy only exposed group with and without the composite adverse pregnancy outcome consisting of stillbirths, spontaneous abortions, and elective terminations.
3. The number of pregnancies by exposure status, regardless of exposure to other MSDMDs, by calendar year of LMP and during the study period.
4. The number of women dispensed IFNB who have been diagnosed with MS and are of childbearing age during the full study period (reference population).

Data management

Data sources

Data source(s), other

National Institute for Health and Welfare (THL) registers: Medical Birth Register (MBR-Fin), Care Register for Health Care, Register of Induced Abortions Finland, National Reimbursement RegisterNational Prescription Register Finland, Medical Birth Register (MBR-Swe) Sweden, National Patient Register (NPR) Sweden, Swedish Prescribed Drug Register (SPDR) Sweden

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Data sources (types)

Administrative healthcare records (e.g., claims)

Disease registry

Drug dispensing/prescription data

Other

Data sources (types), other

Prospective patient-based data collection

Use of a Common Data Model (CDM)

CDM mapping

No

Data quality specifications

Check conformance

Unknown

Check completeness

Unknown

Check stability

Unknown

Check logical consistency

Unknown

Data characterisation

Data characterisation conducted

No