Real-world safety of Copaxone in Offsprings of Breastfeeding and treated RMS pAtients – COBRA study

First published: 29/11/2021

Last updated: 02/04/2024

Study | Finalised

Administrative details

EU PAS number

EUPAS44465

Study ID

44792

DARWIN EU® study

No

Study countries

Germany

Study description

Objective: To assess safety outcomes for offspring breastfed by mothers undergoing glatiramer acetate (GA, Copaxone®) treatment. Methods: This retrospective study used German Multiple Sclerosis and Pregnancy Registry data. Eligible participants had RMS, a live birth, and received GA or no DMT during breastfeeding.

Study status

Finalised

Contact details

Study institution contact

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Study contact

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Primary lead investigator

Kerstin Hellwig

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 17/12/2019

Actual: 17/12/2019

Study start date

Planned: 30/04/2020

Actual: 13/05/2020

Data analysis start date
Planned: 15/06/2020

Actual: 21/08/2020

Date of final study report
Planned: 15/08/2020

Actual: 03/11/2020

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Teva Pharmaceuticals B.V.

Study protocol

EU PAS register_COBRA protocol redacted_FINAL approved.pdf (860.48 KB)

Regulatory

Was the study required by a regulatory body?

No

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

Not applicable

Methodological aspects

Study type

Study type list

Study topic:

Human medicinal product

Disease /health condition

Study type:

Non-interventional study

Scope of the study:

Assessment of risk minimisation measure implementation or effectiveness

Data collection methods:

Secondary use of data

Main study objective:

The objective of study was to assess the outcome of offspring during the initial period of up to 18 months of development who were breastfed by mothers undergoing Glatiramer acetate treatment

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

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

GLATIRAMER ACETATE

Medical condition to be studied

Multiple sclerosis

Breast feeding

Population studied

Short description of the study population

Offspring of mothers with Relapsing Multiple Sclerosis (RMS) who were breast feeding.

Inclusion Criteria

Patients will be included in the study only if they meet all of the following criteria:

- Women with relapsing forms of multiple sclerosis identified by the following:

o Reported diagnosis of RMS

o Pregnancy resulted in live birth

o Reported breastfeeding with no DMT treatment

o Reported breastfeeding under glatiramer acetate

o Gave informed consent and were enrolled into the German Multiple sclerosis and Pregnancy Registry

- Women who have been treated with glatiramer acetate during the breastfeeding period identified by the following:

o Reported glatiramer acetate treatment during entire pregnancy and breastfeeding period OR

o Reported glatiramer acetate treatment initiation during pregnancy and continuation during breastfeeding OR

o Reported glatiramer acetate treatment discontinuation during pregnancy, restart of treatment at some point before delivery and breastfeeding under glatiramer

acetate treatment OR
o Reported glatiramer acetate treatment discontinuation during pregnancy and restart of treatment at some point during breastfeeding OR
o Reported no glatiramer acetate treatment during pregnancy but (re-)start of treatment at some point during breastfeeding
o Reported breastfeeding while under glatiramer acetate treatment for at least one day
- Women who haven’t been treated with any DMT during the breastfeeding period identified by the following:
o Reported DMT discontinuation before conception OR
o Reported DMT discontinuation of glatiramer acetate in the first trimester OR
o Reported no past DMT treatment
o Reported diagnosis of RMS
o Pregnancy resulted in live birth
o Gave informed consent and were enrolled into the German Multiple sclerosis and Pregnancy Registry

Exclusion Criteria
Patients will be excluded from participating in this study if they meet any of the following criteria:
- Women with other forms of multiple sclerosis who breastfed
- Women treated with other DMTs than glatiramer acetate during breastfeeding period

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Age groups

- Term newborn infants (0 – 27 days)
- Infants and toddlers (28 days – 23 months)

Special population of interest

Pregnant women

Estimated number of subjects

120

Study design details

Outcomes

-Frequency (no. of events) and incidence (no. of children with events) of hospitalizations. --Frequency and incidence of antibiotic treatments. - Growth parameters: weight, length and head circumference. - Incidence of Pediatrician reports on children development delay (based on routinely measured parameters: turning, attempt to grasp, sitting, turning towards voices, first words, standing).

Data analysis plan

Summary statistics of study outcome measures were displayed by both study cohorts (GA Cohort and Control Cohort) and overall. Potential lack of balance in risk factors between study cohorts were assessed using a by cohort, side-by-side display of descriptive statistics of the risk factors and their 95% confidence intervals. Incidence tables of binary outcome measures (e.g. proportion of children hospitalized) provided the No. of participants with events and relative percentages as well as the 95% two-sided confidence intervals.. Frequency tables of events (e.g. No. of hospitalizations, No. of relapses) display the annualized number of events as well as its two-sided 95% confidence interval. Descriptive statistics of continuous outcome measures (e.g. weight, head circumference) at end of follow-up duration will include N, mean, SD, SE, Median, IQR min and max values.

Documents

Study results

EU PAS Register_COBRA study report Synopsis_FINAL approved.pdf (368.13 KB)

Data management

ENCePP Seal

The use of the ENCePP Seal has been discontinued since February 2025. The ENCePP Seal fields are retained in the display mode for transparency but are no longer maintained.

Data sources

Data source(s), other

The national German Multiple Sclerosis and Pregnancy Registry

Data sources (types)

Other

Data sources (types), other

Exposure registry

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