Drug utilisation study of macrolide-containing medicinal products during pregnancy

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Study | Finalised

Administrative details

PURI
https://redirect.ema.europa.eu/resource/104297

EU PAS number
EUPAS104296

Study ID
104297

DARWIN EU® study
No

Study countries
France
Germany
United Kingdom

Study description
A a longitudinal observational cohort study to (1) develop and validate a phenotyping algorithm that identifies gestational age, (2) describe the use of macrolides and amoxicillin during pregnancy, and (3) characterise the drug quantity, namely number of units prescribed in tablets or capsules, of Erythromycin by trimester of pregnancy.

Study status
Finalised

Research institution and networks

Institutions

European Medicines Agency (EMA)

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Institution

Contact details

Study institution contact
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Primary lead investigator
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Study timelines

Date when funding contract was signed
Planned:
23/05/2022
Actual:
23/05/2022

Study start date
Planned:
23/05/2022
Actual:
23/05/2022

Date of final study report
Planned:
06/09/2022
Actual:
05/09/2022

Sources of funding

- EMA

Study protocol

Analysis Plan_macrolides_in_pregnancy_20220905_For Publication_CLEAN.pdf(226.75 KB)

Regulatory

Was the study required by a regulatory body?
Yes

Is the study required by a Risk Management Plan (RMP)?
Not applicable

Methodological aspects

Study type

Study type list

Study topic:
Human medicinal product

Study type:
Non-interventional study

Scope of the study:
Drug utilisation

Data collection methods:
Secondary data collection

Main study objective:
To develop and validate a phenotyping algorithm that identifies gestational age, to describe the use of macrolides and amoxicillin during pregnancy (Prescriptions by year, age, gravidity, and trimester of pregnancy, stratified by substance, number of prescriptions and number of distinct substances prescribed by pregnancy, Indications by substance) and to

characterise the drug quantity.

Study Design

Non-interventional study design
Cohort
Other

Non-interventional study design, other
Longitudinal observational study

Study drug and medical condition

Anatomical Therapeutic Chemical (ATC) code
(J01F) MACROLIDES, LINCOSAMIDES AND STREPTOGRAMINS

Population studied

Short description of the study population
The study included pregnant women using a phenotyping algorithm identified from IMRD databases, covering data collection from the start of each database to January 2022.

Age groups
Adults (18 to < 46 years)
Adults (46 to < 65 years)
Adults (65 to < 75 years)
Adults (75 to < 85 years)
Adults (85 years and over)

Special population of interest
Pregnant women

Estimated number of subjects
5012

Study design details

Data analysis plan
A phenotyping algorithm to identify pregnancy start and end dates was developed in OMOP. A descriptive analysis of the use of macrolides and amoxicillin in pregnant women identified using this phenotype. Descriptive statistics and summary tabulations of

prescriptions of macrolides and amoxicillin by year, age group, gravidity (refers to the pregnancy number), trimester and indications, stratified by substance were performed. Trends of use of each substance over time, relative to number of pregnancies as determined by the phenotyping algorithm were also plotted. Drug quantity is reported as pack size, only for standard pack sizes for each solid oral formulation of erythromycin

Documents

Study results
Study Report_macrolides_in_pregnancy_20220905_For Publication_CLEAN.pdf(901.27 KB)

Data management

Data sources

Data source(s)
Disease Analyzer Germany
Disease Analyzer - OMOP

Data source(s), other
IQVIA Medical Research Data EMIS UK

Data sources (types)
Drug dispensing/prescription data
Electronic healthcare records (EHR)

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