Drug utilisation study of macrolide-containing medicinal products during pregnancy

First published: 20/06/2023

Last updated: 20/06/2023

Study Finalised

Administrative details

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 institutions and networks

Institutions

European Medicines Agency (EMA)

First published: 01/02/2024

Last updated: 01/02/2024

Institution

Contact details

Study institution contact

Luis Pinheiro luis.pinheiro@ema.europa.eu

Study contact

luis.pinheiro@ema.europa.eu

Primary lead investigator

Luis Pinheiro

Primary lead investigator

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 use of data

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

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

5.012

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

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)

IQVIA 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