Use of sulfonamide-trimethoprim combinations during pregnancy in IMRD-Germany and IMRD-France

First published: 10/04/2021

Last updated: 30/01/2025

Study Finalised

Administrative details

PURI

https://redirect.ema.europa.eu/resource/40520

EU PAS number

EUPAS40519

Study ID

40520

DARWIN EU® study

No

Study countries

☐ France

Germany

Study description

The aim of this study was to determine the extent of use of sulfonamide and trimethoprim combination products during pregnancy. Use of sulfonamide and trimethoprim combination products was compared to alternative antibiotics: fosfomycin, plain amoxicillin and amoxicillin in combination with clavulanic acid. The type of infection was classified based on recorded ICD codes.

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

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Study contact

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Primary lead investigator

Karin Hedenmalm

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 05/11/2019

Actual: 05/11/2019

Study start date

Planned: 05/11/2019

Actual: 05/11/2019

Date of final study report

Planned: 26/11/2019

Actual: 26/11/2019

Sources of funding

- EMA

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

Disease /health condition

Study type:

Non-interventional study

Scope of the study:

Drug utilisation

Data collection methods:

Secondary use of data

Main study objective:

The aim of this study was to determine the extent of use of sulfonamide and trimethoprim combination products during pregnancy. Use of sulfonamide and trimethoprim combination products was compared to alternative antibiotics: fosfomycin, plain amoxicillin and amoxicillin in combination with clavulanic acid.

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

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

TRIMETHOPRIM

SULFADIAZINE

SULFAMERAZINE

SULFAMETHOXAZOLE

SULFAMETROLE

Population studied

Short description of the study population

Pregnant women who have used sulfonamide and trimethoprim combination products.

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

1000

Study design details

Data analysis plan

All pregnant women, and all use of ‘Co-trimoxazole’, products that contain both trimethoprim and a sulfonamide (sulfadiazine, sulfamerazine, sulfamethoxazole or sulfametrole) as well as fosfomycin and amoxicillin with or without clavulanic acid during pregnancy in women were be captured. The maximum time pregnant (i.e. time window for a possible pregnancy) is calculated from the time point of the recorded pregnancy-related event and the maximum time pregnant for the specific event in accordance with Appendix 1. The denominator is any woman with a pregnancy-related event for which the maximum time pregnant includes the time period. The existence of a prescription for ‘products that contain both trimethoprim and a sulfonamide (sulfadiazine, sulfamerazine, sulfamethoxazole or sulfametrole)’, fosfomycin and amoxicillin during the maximum time pregnant is considered as exposure during pregnancy

Documents

Study results

Sulfonamide Trimethoprim in Pregnancy Results for publication.pdf(257.72 KB)

Data management

Data sources

Data sources (types)

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