Rapid Data Analysis – Ceftriaxone and hepatic events

First published: 23/11/2020

Last updated: 02/07/2024

Study Finalised

Administrative details

EU PAS number

EUPAS38221

Study ID

38276

DARWIN EU® study

No

Study countries

- ☐ France
- ☐ Germany

Study description

This analysis aims to provide descriptive information on specific hepatic events occurring within 30 days of a prescription in patients using ceftriaxone,

stratified by prior history of liver disease or other risk factors for hepatic events. Results are also be stratified by gender, age group, indication, and above or below the mean total dose prescribed on the date of the first prescription. No comparisons to other products will be performed due to the limitations of the data and the low sample size.

Study status

Finalised

Research institutions and networks

Institutions

European Medicines Agency (EMA)

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Institution

Contact details

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Primary lead investigator

Hedenmalm Karin

Primary lead investigator

Study timelines

Date when funding contract was signed
Planned: 01/09/2020

Actual: 01/09/2020

Study start date
Planned: 01/09/2020

Actual: 01/09/2020

Date of final study report
Planned: 18/11/2020

Actual: 18/11/2020

Sources of funding

- EMA

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 topic:

Disease /health condition

Human medicinal product

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:

• What is the incidence of potential hepatotoxic events within 30 days after treatment initiation of ceftriaxone in patients with and patients without a prior history of liver disease or other hepatic risk factors? • What is the incidence of potential hepatotoxic events within 30 days after treatment initiation of ceftriaxone by gender, age group, indication, and dose?

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

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

CEFTRIAXONE

Medical condition to be studied

Liver disorder

Additional medical condition(s)

Hepatic disorder (NOS), toxic liver disease (ICD 10 code K71), Hepatic failure not elsewhere classified (ICD 10 code K72), nonspecific reactive hepatitis (ICD 10 code K75.2), granulomatous hepatitis not elsewhere classified (ICD 10 code K75.3), unspecified and other specified inflammatory liver disease (ICD 10 codes K75.8-K75.9), unspecified and other specified diseases of liver (ICD 10 codes K76.8-K76.9)

Population studied

Short description of the study population

All patients in IMS® Disease Analyzer France and Germany with a ceftriaxone prescription and least 365 days of observation prior to their first ceftriaxone prescription.

Age groups

Preterm newborn infants (0 – 27 days)

Term newborn infants (0 – 27 days)

Infants and toddlers (28 days – 23 months)

Children (2 to < 12 years)

Adolescents (12 to < 18 years)

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

Hepatic impaired

Estimated number of subjects

100

Study design details

Outcomes

• toxic liver disease (ICD 10 code K71) • hepatic failure not elsewhere classified (ICD 10 code K72) • nonspecific reactive hepatitis (ICD 10 code K75.2) • granulomatous hepatitis not elsewhere classified (ICD 10 code K75.3) • unspecified and other specified inflammatory liver disease (ICD 10 codes K75.8-K75.9) • unspecified and other specified diseases of liver (ICD 10 codes K76.8-K76.9)

Data analysis plan

The incidence rate of hepatic outcome events during a maximum of 30 days of follow-up after each ceftriaxone prescription has been calculated per 1000 person-years of follow-up in each subgroup and stratum. Only the first hepatic outcome event after start of ceftriaxone and the time until the first hepatic outcome event is considered. Separate results are presented for some specific risk factors. Results are also stratified by gender, age group at first ceftriaxone prescription (0-17 years, 18-49 years, 50-69 years and ≥70 years), indication at first ceftriaxone prescription (upper respiratory tract infection, lower respiratory tract infection, ear infection, urinary tract infection, genital infection, prostate

infection, testicular infection, gastrointestinal infection, skin/soft tissue infection, bone infection, borrelia (Lyme disease), central nervous system infection, other infection), and total dose at first ceftriaxone prescription.

Documents

Study results

RDA-Ceftriaxone_results_redacted-for-publication.pdf(837.38 KB)

Data management

Data sources

Data source(s), other

IMS LifeLink EMR France, IQVIA Disease Analyzer Germany

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