Indications for systemic fluoroquinolone prescribing in Europe: a descriptive population based study

First published: 06/09/2017

Last updated: 02/07/2024

Study Finalised

Administrative details

EU PAS number

EUPAS20889

Study ID

25386

DARWIN EU® study

No

Study countries

France

Germany

United Kingdom

Study description

A descriptive analysis of indications for treatment with systemic fluoroquinolone antibiotics in Summary of Product Characteristics across the European Economic Area (EEA) will first be conducted. Secondly a descriptive analysis of clinical indications for treatment with systemic fluoroquinolone antibiotics in France, Germany and UK will be conducted using electronic health records. Time trends in fluoroquinolone antibiotic use will be evaluated. Indications for acute sinusitis, acute bronchitis and uncomplicated urinary tract infection will specifically be evaluated.

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

Daniel Morales

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 10/10/2016

Actual: 10/10/2016

Study start date

Planned: 17/10/2016

Actual: 17/10/2016

Data analysis start date

Planned: 14/11/2016

Actual: 14/11/2016

Date of final study report

Planned: 13/11/2017

Actual: 06/08/2018

Sources of funding

- EMA

Study protocol

EUPAS20889.protocol.pdf (60 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:

Disease /health condition

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 provide a descriptive analysis of broad indications for treatment with systemic fluoroquinolone antibiotics in Summary of Product Characteristics across the European Economic Area (EEA). To provide a descriptive analysis of clinical indications for treatment with systemic fluoroquinolone antibiotics in France, Germany and UK electronic health records

Study Design

Non-interventional study design

Other

Non-interventional study design, other

Descriptive analysis

Study drug and medical condition

Anatomical Therapeutic Chemical (ATC) code

(J01MA) Fluoroquinolones

Fluoroquinolones

Medical condition to be studied

Sinusitis

Bronchitis

Urinary tract infection

Population studied

Short description of the study population

Patients were included from the IMS® Disease Analyzer France and Germany with a minimum period of 1 year follow-up defined according to their consultation and prescribing observability.

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

Other

Special population of interest, other

Sinusitis, Bronchitis, Urinary tract infection patients

Estimated number of subjects

200.000

Study design details

Outcomes

1) Descriptive analysis of the proportion of Summary of Product Characteristics across Europe with an indication for treatment for different indication categories. 2) Broad clinical indications for incident fluoroquinolone antibiotic prescribing in primary care.

Data analysis plan

The Summary of Product Characteristics for fluoroquinolone containing antibiotic products will be screened to identify what proportion have an indication listed for sinusitis, bronchitis and urinary tract infection. Incident fluoroquinolone prescriptions will be identified for adults in each electronic health record database. Read and ICD codes will be screened to identify the likely clinical indication for such recording. These will be broadly categorised according to different systems and specific information provided for sinusitis, bronchitis and urinary tract infection cross-sectionally. Time trends in the use of incident fluoroquinolone antibiotics will be provided for different broad system categories including for sinusitis, bronchitis and urinary tract infection for each database were data is available.

Documents

Study results

Summary.results.pdf (120.24 KB)

Study publications

Morales DR, Slattery J,Pinheiro L, Kurz X, Hedenmalm K. Indications for Systemi…

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)

THIN® (The Health Improvement Network®)

IQVIA Disease Analyzer Germany

Disease Analyzer - OMOP

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

Unknown