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

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Study Finalised

Administrative details

PURI
https://redirect.ema.europa.eu/resource/25386

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 institution and networks

Institutions

European Medicines Agency (EMA)
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Institution

Contact details

Study institution contact
Daniel Morales
Study contact

Daniel.Morales@ext.ema.europa.eu
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 data collection

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

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
200000

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

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

Data management

Data sources

Data source(s)
THIN® (The Health Improvement Network®)
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