Risk of peripheral neuropathy with systemic fluoroquinolone exposure: population-based nested case-control study

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Study Finalised

Administrative details

PURI

https://redirect.ema.europa.eu/resource/29759

EU PAS number

EUPAS27627

Study ID

29759

DARWIN EU® study

No

Study countries

☐ United States

Study description

Nested case-control study examining the risk of incidence peripheral neuropathy with systemic fluoroquinolone exposure in primary care using co-amoxiclav exposure as a negative control.

Study status

Finalised

Research institutions and networks

Institutions

European Medicines Agency (EMA)

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Institution

Contact details

Study institution contact

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Study contact

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Primary lead investigator

Daniel Morales

Primary lead investigator

Study timelines

Date when funding contract was signed
Planned: 04/09/2017

Actual: 04/09/2017

Study start date
Planned: 06/11/2017

Actual: 06/11/2017

Data analysis start date
Planned: 08/01/2018

Actual: 08/01/2018

Date of final study report
Planned: 03/09/2018

Actual: 15/05/2019

Sources of funding

- EMA

Study protocol

EUPASneuropathy.protocol.pdf(63.95 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:

Assessment of risk minimisation measure implementation or effectiveness

Data collection methods:

Secondary use of data

Main study objective:

Estimate the risk of incident peripheral neuropathy associated with systemic fluoroquinolone exposure in primary care using systemic co-amoxiclav exposure

as a negative control.

Study Design

Non-interventional study design

Case-control

Study drug and medical condition

Anatomical Therapeutic Chemical (ATC) code

(J01MA) Fluoroquinolones

Fluoroquinolones

Medical condition to be studied

Neuropathy peripheral

Population studied

Short description of the study population

Adults aged 18 years or over identified from THIN database between January 1, 1999 and December 31, 2015 issued at least one prescription of co-amoxiclav or fluoroquinolone antibiotic product with a systemic route of administration.

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)

Estimated number of subjects

50000

Study design details

Outcomes

Incident peripheral neuorpathy cases recorded within primary care electronic medical records using Read codes.

Data analysis plan

Cases and controls will be identified from a cohort of adults prescribed antibiotics within the THIN database. Conditional logistic regression will be used to estimate odds ratios (that will approximate incidence rate ratios with risk set sampling) for the association between systemic fluoroquinolone and co-amoxiclav exposure and incident peripheral neuropathy in adults without diabetes. Adjustment will be made for age, sex, calendar time, general practice, comorbidity (charlson score), history of SLE, sjogrens, shingles, amyloidosis Lyme disease, and exposure to phenytoin, metronidazole, and nitrofurantoin therapy.

Documents

Study results

EUPAS20889 abstract results.pdf(152.29 KB)

Study publications

Morales D, Pacurariu A, Slattery J, Pinheiro L, McGettigan P, Kurz X. Associati...

Data management

Data source(s)

THIN® (The Health Improvement Network®)

Data source(s), other

THIN

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