

# 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 institution and networks

# Institutions

## European Medicines Agency (EMA)

**First published:** 01/02/2024

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Institution

## Contact details

### Study institution contact

Daniel Morales

Study contact

[Daniel.Morales@ext.ema.europa.eu](mailto:Daniel.Morales@ext.ema.europa.eu)

### Primary lead investigator

Daniel Morales

Primary lead investigator

## Study timelines

### Date when funding contract was signed

Planned:

04/09/2017

Actual:

04/09/2017

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### Study start date

Planned:

06/11/2017

Actual:

06/11/2017

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### Data analysis start date

Planned:

08/01/2018

Actual:

08/01/2018

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### 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

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**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

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**Study type:**

Non-interventional study

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**Scope of the study:**

Assessment of risk minimisation measure implementation or effectiveness

**Data collection methods:**

Secondary data collection

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**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

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**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.

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**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)

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**Estimated number of subjects**

50000

## Study design details

## Outcomes

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

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## 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)

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### Study publications

[Morales D, Pacurariu A, Slattery J, Pinheiro L, McGettigan P, Kurz X. Associati...](#)

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## Data management

### Data sources

#### Data source(s)

THIN® (The Health Improvement Network®)

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#### Data source(s), other

THIN

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#### Data sources (types)

[Electronic healthcare records \(EHR\)](#)

### Use of a Common Data Model (CDM)

#### CDM mapping

No

### Data quality specifications

**Check conformance**Unknown

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**Check completeness**Unknown

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**Check stability**Unknown

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**Check logical consistency**

Unknown

## Data characterisation

**Data characterisation conducted**

Unknown