The Use of Oral Fluoroquinolones in Canada: Drug Utilization Study Update

First published: 24/10/2023

Last updated: 03/04/2025

Study Finalised

Administrative details

EU PAS number

EUPAS107333

Study ID

108049

DARWIN EU® study

No

Study countries

☐ Canada

Study description

In January 2017, Health Canada issued a risk communication to restrict the use of fluoroquinolone antibiotics due their disabling and potentially persistent side effects. The labelling of all systemic fluoroquinolones available in Canada were

updated accordingly. There is a need to determine if fluoroquinolone utilization patterns have changed since these regulatory actions were implemented. The main objectives of this study are to update our previous study to describe fluoroquinolone utilization trends from 2008 to 20022 and to assess the impact of the risk minimization measures introduced in 2017. We will conduct a retrospective cohort study using administrative health databases from 6 provinces (Alberta, British Columbia, Manitoba, Nova Scotia, Ontario, and Saskatchewan) between January 1, 2008 and December 31, 2022. Similar methods to the previous CNODES drug utilization study will be used. We will assess utilization patterns and indications of systemic oral fluoroquinolones available in Canada from 2008 to present. In addition, we will assess the impact of the 2017 risk minimization measures (risk communication, updates to the labels) on the use of fluoroquinolones through a time series analysis. These findings will provide important insight on the current trends of fluoroquinolones use in Canada. The study will only include prescriptions for the oral formulation of fluoroquinolones and will not include fluoroquinolone prescriptions dispensed in hospital.

Study status

Finalised

Research institutions and networks

Institutions

Lady Davis Institute

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Institution

Contact details

Study institution contact

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Study contact

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Primary lead investigator

Pierre Ernst

Primary lead investigator

Study timelines

Date when funding contract was signed

Actual: 06/10/2023

Study start date

Planned: 01/02/2024

Actual: 23/10/2023

Data analysis start date

Planned: 01/02/2024

Actual: 01/12/2023

Date of interim report, if expected

Planned: 01/03/2024

Actual: 01/03/2024

Date of final study report
Planned: 30/04/2024

Actual: 30/04/2024

Sources of funding

- Other

More details on funding

CADTH (Canadian Agency for Drugs and Technologies in Health)

Study protocol

Fluoroquinolones-Protocol.pdf (578.81 KB)

Regulatory

Was the study required by a regulatory body?

Yes

Is the study required by a Risk Management Plan (RMP)?

Not applicable

Methodological aspects

Study type

Study type list

Study topic:

Human medicinal product

Study type:

Non-interventional study

Main study objective:

The main objective of this study are to update our previous study to describe fluoroquinolone utilization trends from 2008 to 20022 and to assess the impact of the risk minimization measures introduced in 2017.

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

Anatomical Therapeutic Chemical (ATC) code

(J01MA02) ciprofloxacin

ciprofloxacin

(J01MA06) norfloxacin

norfloxacin

(J01MA12) levofloxacin

levofloxacin

(J01MA14) moxifloxacin

moxifloxacin

Population studied

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)

Estimated number of subjects

4850000

Study design details

Data analysis plan

We will first assess utilization patterns and indications for oral fluroquinolones available in Canada from 2008 to 2022. We will estimate the yearly fluoroquinolone dispensation rates (per 1,000 population) overall and by molecule. We will describe fluoroquinolone use by dosage and duration of use, by prescriber group or specialty, and frequent indications associated with their use. For 3 indications of interest (see section 7), we will determine the rate and percentage of prescriptions for fluoroquinolones vs. other antibiotics, for adults with uncomplicated disease. In addition, we will assess the impact of the regulatory actions on fluoroquinolone use over time. A segmented regression model will be used to compare the rate of fluoroquinolone dispensations before and after 2017, and the rates of fluoroquinolone vs. other antibiotics for the 3

indications of interest. Results will be reported by provinces, pooled, and by age group and sex.

Documents

Report

Link to project page on CNODES website

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), other

Provincial administrative health databases Canada

Data sources (types)

Administrative healthcare records (e.g., claims)

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