Association between opioid use and the development of diverticulitis (Opioids Diverticulitis)

First published: 07/08/2023

Last updated: 12/02/2025

Study Finalised

Administrative details

EU PAS number

EUPAS104164

Study ID

104165

DARWIN EU® study

No

Study countries

- ☐ Canada
- ☐ United Kingdom
- ☐ United States

Study description

While opioid use has been established as a risk factor for diverticulitis, there is limited evidence on the association between opioid analgesics and diverticulitis. The objective of this study is to evaluate whether opioid use is associated with elevated risk of diverticulitis in patients indicated for treatment with opioids. We will carry out separate population-based cohort studies using administrative health databases from five Canadian provinces, the United Kingdom, and the United States. Results from the separate sites will be combined to provide an overall assessment of the risk of diverticulitis in users of opioids.

Study status

Finalised

Research institutions and networks

Institutions

Lady Davis Institute

First published: 01/02/2024

Last updated: 01/02/2024

Institution

Clinical Practice Research Datalink (CPRD)

United Kingdom

First published: 15/03/2010

Last updated: 17/01/2025

Institution | Laboratory/Research/Testing facility | ENCePP partner

University of British Columbia

First published: 01/02/2024

Last updated: 01/02/2024

Institution

University of Calgary Calgary, Canada, University of British Columbia (British Columbia and MarketScan) Vancouver, Canada, University of Manitoba Winnipeg, Canada, ICES Toronto, Canada, Saskatchewan Health Quality Council Saskatoon, Canada, Lady Davis Institute (CPRD) Montreal, Canada

Contact details

Study institution contact

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Study contact

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Primary lead investigator

Michael Webster-Clark

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 09/12/2022

Actual: 09/12/2022

Study start date

Planned: 20/03/2023

Actual: 20/03/2023

Data analysis start date

Planned: 20/03/2023

Actual: 20/03/2023

Date of final study report

Planned: 30/11/2023

Actual: 08/08/2024

Sources of funding

- Other

More details on funding

CADTH (Canadian Agency for Drugs and Technologies in Health)

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 type:

Non-interventional study

Scope of the study:

Assessment of risk minimisation measure implementation or effectiveness

Drug utilisation

Main study objective:

The main objective of this multi-centre population-based study is to evaluate whether opioid use is associated with elevated risk of diverticulitis in patients indicated for treatment with opioids.

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

Anatomical Therapeutic Chemical (ATC) code

(N02AA) Natural opium alkaloids

Natural opium alkaloids

(N02AB) Phenylpiperidine derivatives

Phenylpiperidine derivatives

(N02AC) Diphenylpropylamine derivatives

Diphenylpropylamine derivatives

(N02AD) Benzomorphan derivatives

Benzomorphan derivatives

(N02AE) Oripavine derivatives

Oripavine derivatives

(N02AF) Morphinan derivatives

Morphinan derivatives

(N02AJ) Opioids in combination with non-opioid analgesics

Opioids in combination with non-opioid analgesics

(N02AX) Other opioids

Other opioids

(N07BC) Drugs used in opioid dependence

Drugs used in opioid dependence

Medical condition to be studied

Diverticulitis

Additional medical condition(s)

Three indications for the initiation of opioid treatment: 1) post-surgical pain, 2) post-trauma pain, and 3) other pain indications.

Population studied

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

24369137

Study design details

Outcomes

The risk of diverticulitis will be assessed on the landmark date (see follow-up section below) by an emergency department or inpatient primary discharge diagnosis of diverticulitis. Severe diverticulitis will be defined as an inpatient primary discharge diagnosis of diverticulitis with an accompanying computed tomography (CT) scan. The risks will be assessed within 30, 180, and 730 days.

Data analysis plan

Three indication cohorts for opioid treatment (defined above) between 2004-2020 will be created in each site, with patients allowed into multiple cohorts. Analyses will be conducted using inverse probability of treatment weights and odds weights separately. Patient characteristics and prevalence of opioids use

(new use, prevalent use, and non-use) will be described for each indication. Incidence rate ratios and differences, and risk ratios and differences of diverticulitis (defined above) will be estimated among prevalent and non-users of opioids compared with new users. Follow-up will be defined using both an intention-to-treat and an as-treated approach (with inverse probability of censoring weights). Subgroups analyses (if feasible) by sex, age, and sub-class of surgical indication will be conducted. Patients with prevalent or new use of opioid maintenance therapy will be excluded in a sensitivity analysis. Site-specific results will be pooled using random effects meta-analysis.

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)

Clinical Practice Research Datalink

Data source(s), other

Provincial administrative health databases Canada, MarketScan Commercial and Medicare databases United States

Data sources (types)

Administrative healthcare records (e.g., claims)

Drug dispensing/prescription data

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

No