Determining the impact of opioid policy on intended and unintended harms: a data linkage study

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Study Planned

Administrative details

EU PAS number

EUPAS104005

Study ID

104006

DARWIN EU® study

No

Study countries

Australia

Study description

Increasing harms related to prescription opioids over the past decade has led to the introduction of a range of key national and state policy initiatives across Australia. However, similar opioid policies internationally have had mixed outcomes, including unintended adverse consequences. There is little real-world evidence on how these policy levers work in Australia. the current study seeks to examine the impact of introducing a range of opioid-related policies on hospital admissions and emergency department (ED) presentations, in Victoria, Australia. In particular, the study aims to understand the effect of various opioid policy and opioid prescribing changes on: (1) The number and rates of ED presentations and hospital admissions attributed to substance use (i.e opioid and non-opioid related), or mental ill-health (e.g. suicide, self-harm, anxiety, depression), (2) the association between differing opioid dose trajectories and the likelihood of ED presentations and hospital admissions related to substance use and mental ill-health, (3) whether changes in an individual's opioid prescribing changes the risk related to ED presentations and hospital admissions related to substance use and mental ill-health, after considering other confounding factors, using a case-control design. Interrupted time series (ITS) will be used to examine the impact of opioid policies on a range of harms including the incidence of presentations related to substance use (opioid and non-opioid), and mental ill-health among the primary care cohort. Group-based trajectory modelling and a case-crossover design will be used to further explore the impact of changes in opioid dosage and other covariates on opioid and non-opioid poisonings, and mental ill-health related presentations at the patient-level.

Study status

Planned

Research institutions and networks

Institutions

Monash University

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Institution

Contact details

Study institution contact

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Study contact

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Primary lead investigator

Nielsen Suzanne

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 01/01/2021

Study start date

Planned: 30/06/2022

Date of final study report
Planned: 31/12/2023

Sources of funding

- Other

More details on funding

Australian NHMRC

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 type:

Non-interventional study

Scope of the study:

Disease epidemiology

Drug utilisation

Main study objective:

Using a linked dataset, this project aims to examine if changes to opioid prescribing policies have impacted prescription opioid-related harms.

Study Design

Non-interventional study design

Cohort

Other

Non-interventional study design, other

Case-crossover

Population studied

Age groups

- 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

60.000

Study design details

Outcomes

The main outcomes of interest are ED presentations and hospital admissions attributed to substance use (both opioid and non-opioid) or mental ill-health (e.g. suicide, self-harm, anxiety, depression). We focus on these outcomes as opioid and non-opioid-related substance use, mental health crises and suicide have all been demonstrated to be key outcomes related to changes in opioid prescribing.

Data analysis plan

This is a population linked data study using data from general practice health records obtained from the Population Level Analysis and Reporting (POLAR) platform and linked with person-level data from three large hospital networks in Victoria, Australia. Interrupted time series (ITS) will be used to examine the impact of opioid policies on a range of harms including the incidence of presentations related to substance use (opioid and non-opioid), and mental ill-health among the primary care cohort. Group-based trajectory modelling and a case-crossover design will be used to further explore the impact of changes in opioid dosage and other covariates on opioid and non-opioid poisonings, and mental ill-health related presentations at the patient-level.

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.

Signed checklist for study protocols

ENCePP Checklist_EUPAS104005.pdf (441.66 KB)

Data sources

Data sources (types)

Electronic healthcare records (EHR)

Other

Data sources (types), other

Hospital admissions and emergency department presentations data

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