Using primary care data to understand Opioid Prescribing, Policy Impacts and Clinical Outcomes: A protocol for the OPPICO Study

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Study Planned

Administrative details

EU PAS number

EUPAS43218

Study ID

43219

DARWIN EU® study

No

Study countries

Australia

Study description

Australia has seen a near doubling of opioid-related mortality in the past decade, with many of these harms linked to prescription opioids. Recently, a key strategy to attempt to reduce opioid-related harm has been through state and national policy-led changes in prescribing, including ‘upscheduling’ medicines (e.g. from over-the-counter to prescription only), implementing prescription monitoring systems (e.g. surveillance that flags high-risk prescribing & patients), and reducing pack sizes to limit supply. Few studies have specifically explored intended and unintended outcomes of these changes. In Australia, nearly half of all opioids are prescribed in primary care. This makes it important to understand how opioid prescribing within these settings are influenced by policy. Using primary care data, the study will provide new insights into opioid prescribing including the impact of policy and patient characteristics on opioid prescribing. The specific aims are: 1)To evaluate the impact of recent Australian and Victorian policies on opioid prescribing in primary care, including but not limited to codeine rescheduling, clinical guideline implementation and prescription monitoring programs, 2)To understand the impact of recent Australian primary care opioid prescribing guideline recommendations on specific conditions, 3) To examine the different patterns and outcomes of opioid cessation and 4) To explore the use and correlates of non-opioid and non-pharmacological approaches among people prescribed opioids. We will conduct a retrospective cohort analysis of patients prescribed opioids using a range epidemiological approaches. This will include interrupted time series analysis to evaluate the impact of policies on opioid prescribing.

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

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Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 01/01/2021

Actual: 01/01/2021

Study start date

Planned: 15/01/2021

Date of final study report
Planned: 29/12/2023

Sources of funding

- Other

More details on funding

Australian NHMRC, University PhD Scholarships

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:

To evaluate the impact of recent Australian policies on opioid prescribing in primary care, understand the impact of recent Australian primary care opioid prescribing guideline recommendations on specific conditions, use exploratory analysis to examine the different patterns and outcomes of opioid cessation, and explore the use and correlates of non-opioid and non-pharmacological interventions.

Study Design

Non-interventional study design

Cohort

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

700000

Study design details

Outcomes

Opioid exposure: Opioid prescribing (e.g. change in primary care in opioid dose, opioid initiation and cessation, and prescribing patterns within specific populations), Utilisation of non-opioid medicines: Average daily doses of non-opioid types of medicines commonly used among people prescribed opioids (e.g. analgesics, gabapentinoids, benzodiazepines). Utilisation of non-pharmacological interventions: Non-pharmacological interventions will be defined as referrals to relevant healthcare providers.

Data analysis plan

To explore the changes in opioid prescribing after policy change, interrupted time series analyses will be used. Descriptive statistics will be used to describe the demographic and other characteristics of the cohort prescribed opioids prior to and after the policy change. Multivariable logistic regressions will be then used to examine predictors of receiving an opioid prescription pre and post policy change. Differences between groups in terms of odds of opioid use will be expressed as Odds Ratios (ORs) derived from logistic regressions. To explore the patterns of opioid cessation among long term opioid users, group-based trajectory modelling will be used to determine determine key subgroups of people prescribed and ceased opioids and compare outcomes for each of the trajectories via stand-alone trajectory modelling. Multinomial regression and descriptive analysis will be used to examine our sample characteristics that are

associated with trajectory groups.

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 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

No