DARWIN EU® Drug utilization study of prescription opioids

First published: 04/07/2023

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Study Finalised

Administrative details

EU PAS number

EUPAS105641

Study ID

106383

DARWIN EU® study

Yes

Study countries

- [ ] Belgium
- [ ] Estonia
- [ ] France
- [ ] Germany
- [ ] Netherlands
- [ ] Spain

Study description

Prescription opioids, while effective for managing severe pain, have led to a public health crisis due to misuse, addiction, and overdose, particularly in the US.

Recently, concerns have been growing in Europe due to increasing opioid use and related mortality.

Factors such as chronic pain, mental health disorders, and advanced age can exacerbate misuse and the development of dependence.

Given the potential for global spread of this issue, enhanced surveillance and in-depth research into opioid utilization patterns are imperative.

A drug utilization study using a Common Data Model (CDM) is a promising approach to supplement European opioid monitoring systems, providing more granular data to inform evidence-based decisions on this complex topic.

The European Medicines Agency commissioned this DARWIN EU© CC study to:

(i) To investigate the annual incidence and annual period prevalence of use of opioids (overall, active drug substance, strength (weak/strong opioids) and route (oral, transdermal or parenteral)), stratified by calendar year, age, sex and country/database during the study period 2012-2022.

(ii) To determine duration of prescription opioid use, as well as characteristics of new users and indication for opioid prescribing/dispensing, all stratified by calendar year and country/database.

Study status

Finalised

Contact details

Study institution contact

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Study contact

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Primary lead investigator

Annika Jodicke

Primary lead investigator

Study timelines

Date when funding contract was signed

Actual: 30/03/2023

Study start date

Actual: 01/01/2012

Date of final study report

Actual: 06/11/2023

Study protocol

Study Protocol P2 C1-002 Version 2.1 final.pdf(1.78 MB)

Regulatory

Was the study required by a regulatory body?

Yes

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

Not applicable

Other study registration identification numbers and links

EUPAS1000000479

EUPAS1000000615

Methodological aspects

Study type

Study type list

Study type:

Non-interventional study

Scope of the study:

Drug utilisation

Main study objective:

(i) To investigate the annual incidence and annual period prevalence of use of opioids stratified by calendar year, age, sex and country/database during the study period 2012-2022.
(ii) To determine duration of prescription opioid use, as well as characteristics of new users and indication for opioid prescribing/dispensing, all stratified by calendar year and country/database.

Study drug and medical condition

Study drug International non-proprietary name (INN) or common name

BUPRENORPHINE

NALOXONE HYDROCHLORIDE DIHYDRATE

OXYCODONE

PENTAZOCINE

TILIDINE

Anatomical Therapeutic Chemical (ATC) code

(N01AH) Opioid anesthetics

Opioid anesthetics

(N02AX) Other opioids

Other opioids

(R05DA) Opium alkaloids and derivatives

Opium alkaloids and derivatives

Population studied

Age groups

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

19000000

Study design details

Data analysis plan

Population-level opioid use: Annual period prevalence of opioid use and annual incidence rates per 100,000 person years will be estimated.

Patient-level opioid use: Large-scale patient-level characterization will be conducted at index date, including patient demographics, and history of comorbidities and comedication.

Frequency of indication at index date, and in the immediate time before will be calculated.

Cumulative treatment duration will be estimated for the first treatment era and the minimum, p25, median, p75, and maximum will be provided.

For all analyses a minimum cell count of 5 will be used when reporting results, with any smaller counts will be noted as <5.

Documents

Study report

DARWIN_EU_StudyReport_P2_C1_002_Opioids_V3_final_EUPAS.pdf(9.16 MB)

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)

The Information System for Research in Primary Care (SIDIAP)

Integrated Primary Care Information (IPCI)

IQVIA Longitudinal Patient Data - Belgium

IQVIA Disease Analyzer Germany

Auria Clinical Informatics (FinOMOP)

Estonian Biobank

Clinical Data Warehouse of the Bordeaux University Hospital

Data sources (types)

Electronic healthcare records (EHR)

Other

Use of a Common Data Model (CDM)

CDM mapping

Yes

CDM Mappings

CDM name

OMOP

CDM website

https://www.ohdsi.org/Data-standardization/

Data quality specifications

Check conformance

Unknown

Check completeness

Unknown

Check stability

Unknown

Check logical consistency

Unknown

Data characterisation

Data characterisation conducted

No