

DARWIN EU® Drug Utilisation Study of prescription opioids

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Study

Ongoing

Administrative details

PURI

<https://redirect.ema.europa.eu/resource/1000000479>

EU PAS number

EUPAS1000000479

Study ID

1000000479

DARWIN EU® study

Yes

Study countries

Belgium

Denmark

Estonia

- France
 - Netherlands
 - Norway
 - 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.

Study status

Ongoing

Research institutions and networks

Institutions

Department of Medical Informatics - Health Data Science, Erasmus Medical Center (ErasmusMC)

Netherlands

First published: 03/11/2022

Last updated: 02/05/2024

Institution

Educational Institution

ENCePP partner

Networks

Data Analysis and Real World Interrogation Network (DARWIN EU®)

Belgium

Croatia

Denmark

Estonia

Finland

France

Germany

Hungary

Netherlands

Norway

Portugal

Spain

United Kingdom

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Network

Contact details

Study institution contact

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Study contact

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Primary lead investigator

Amy Lam

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 04/09/2024

Actual: 04/09/2024

Study start date

Planned: 04/02/2025

Actual: 04/02/2025

Date of final study report

Planned: 30/04/2025

Sources of funding

- EMA

Study protocol

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

Data collection methods:

Secondary use of data

Study design:

A cohort study will be conducted using routinely-collected health data from 8 databases.

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

Name of medicine, other

Opioids (substances listed in ATC classes N01AH, N02A and R05DA),, namely: acetyldihydrocodeine, alfentanil, anileridine, bezitramide, butorphanol, buprenorphine, codeine, dezocine, dimemorfan, dextromethorphan, dextromoramide, dextropropoxyphene, dihydrocodeine, ethylmorphine, fentanyl, hydrocodone, hydromorphone, ketobemidone, meptazinol, meperidine (pethidine), methadone, morphine, nicomorphine, normethadone, nalbuphine, noscapine, oliceridine, opium, oxycodone, oxymorphone, papaveretum, pentazocine, phenazocine, phenoperidine, pholcodine, piritramide, propoxyphene, remifentanil, sufentanil, tapentadol, thebacon, tilidine, tramadol; naloxone; buprenorphine/naloxone, oxycodone/naloxone, pentazocine/naloxone, tilidine/naloxone

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

BUTORPHANOL

BUPRENORPHINE

CODEINE

DEXTROMETHORPHAN

DIHYDROCODEINE

ETHYLMORPHINE

FENTANYL

HYDROMORPHONE

METHADONE

MORPHINE
OXYCODONE
PENTAZOCINE
PHOLCODINE
SUFENTANIL
TAPENTADOL
TILIDINE
TRAMADOL
NALOXONE

Anatomical Therapeutic Chemical (ATC) code

(N01AH) Opioid anesthetics

Opioid anesthetics

(N02A) OPIOIDS

OPIOIDS

(R05DA) Opium alkaloids and derivatives

Opium alkaloids and derivatives

Population studied

Short description of the study population

The study cohort will comprise all individuals present in the database during the study period (2012-2024) and with at least 365 days of data availability before the day they become eligible for study inclusion. Therefore, children aged <1 year will be excluded.

Age groups

All

Paediatric Population (< 18 years)

Children (2 to < 12 years)

Adolescents (12 to < 18 years)
Adult and elderly population (≥ 18 years)
Adults (18 to < 65 years)
Adults (18 to < 46 years)
Adults (46 to < 65 years)
Elderly (≥ 65 years)
Adults (65 to < 75 years)
Adults (75 to < 85 years)
Adults (85 years and over)

Data management

Data sources

Data source(s)

Estonian Biobank
IQVIA Longitudinal Patient Data - Belgium
Integrated Primary Care Information (IPCI)
The Information System for Research in Primary Care (SIDIAP)
Clinical Data Warehouse of the Bordeaux University Hospital
Danish Health Data Registries
Institut Municipal d'Assistència Sanitària Information System
Norwegian Linked Health registry at University of Oslo

Use of a Common Data Model (CDM)

CDM mapping

Yes

CDM Mappings

CDM name

OMOP

CDM website

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

CDM version

<https://ohdsi.github.io/CommonDataModel/index.html>

Data quality specifications

Check conformance

Unknown

Check completeness

Unknown

Check stability

Unknown

Check logical consistency

Unknown

Data characterisation

Data characterisation conducted

Unknown