DARWIN EU® Drug Utilisation Study of prescription opioids

First published: 11/02/2025

Last updated: 07/03/2025

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

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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

DARWIN EU Protocol_P3-C2-002_DUS Opioids_V3.pdf(862.45 KB)

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, pirinitramide, propoxyphene, remifentanil, sufentanil, tapentadol, thebacon, tilidine, tramadol; naloxone; buprenorphine/naloxone, oxycodone/naloxone,pentazocine/naloxone, tilidine/naloxone

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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