Opioids prescription in the Valencia Region: Patterns of Use, Misuse and Trends 2011-2017. A Population-based Real World Data Cohort

First published: 28/03/2019

Last updated: 03/04/2020

Study Finalised

Administrative details

EU PAS number

EUPAS28864

Study ID

34548

DARWIN EU® study

No

Study countries

☐ Spain

Study status

Finalised

Research institutions and networks

Institutions

The Foundation for the Promotion of Health and Biomedical Research of Valencia Region (FISABIO)

Spain

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Last updated: 31/10/2025

Institution

Contact details

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Study contact

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Primary lead investigator

Salvador Peiró

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 03/12/2018

Actual: 03/12/2018

Study start date
Planned: 15/04/2019

Actual: 12/03/2019

Date of final study report
Planned: 15/12/2021

Actual: 12/03/2019

Sources of funding

- Pharmaceutical company and other private sector
- Other

More details on funding

GRUNENTHAL (partial funding, covers only some objectives), FISABIO

Study protocol

20190211 01_1 OPIOIDS_V1_0 PROTOCOL.pdf (1.19 MB)

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 topic:

Other

Study topic, other:

Disease/Epidemiology study

Study type:

Non-interventional study

Scope of the study:

Disease epidemiology

Drug utilisation

Data collection methods:

Secondary use of data

Main study objective:

To create a cohort of patients initiating with opioids in the region of Valencia to study:- indicence and prevalence of use of opioids and the impact of the june 2018 informative note of the AEMPS (objectives funded by Grunenthal)- appropiateness of prescription and management of episodes, and the relation between treatment duration and opiod-related events (not funded by Grunenthal)

Study Design

Non-interventional study design

Cohort

Population studied

Short description of the study population

Persons 18 years of age or older (turned between 2011 and 2018) who have at least least one prescription or dispensing of an opioid registered in the Pharmaceutical provision information system (GAIA) of SVS Data Warehouse.

Age groups

- 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)

Special population of interest

Renal impaired

Hepatic impaired

Immunocompromised

Pregnant women

Estimated number of subjects

150000

Study design details

Data analysis plan

Baseline characteristics will be described, total and stratified by type of pain (oncologic, chronic non-oncologic, other) and duration of treatment. Proportion of inappropiate prescription will be provided using several indicators. Use of healthcare resources in the year following start on opiods will be accounted. Crude and standardized use rates and time series will be constructed to picture

evolution of use. Interrupted time serie analysis will be used to assess the impact of 2008 AEMPS note, using Prais-Winsten models with Cochrane-Orcutt transformation and Durbin-Watson test to assess autocorrelation correction. Multilevel regression analysis will be used to assess the association between treatment duration and opiod-related events, with patient factors in first level, basic health zone in second and health department in third level.

Documents

Study, other information

20190211 01_2 OPIOIDS_V0_02 ANEXOS.pdf (1.44 MB)

Informe FIS-FEN-2019-01.pdf (101.1 KB)

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)

Administrative healthcare records (e.g., claims)

Drug dispensing/prescription data

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