An Observational Post-Authorisation Safety Study (PASS) of Patients with Chronic Opioid Use for Non-Cancer Pain and Cancer Pain who have Opioid-Induced Constipation (OIC) (Naldemedine PASS)

First published: 27/09/2021

Last updated: 23/04/2024

Study Planned

Administrative details

PURI

https://redirect.ema.europa.eu/resource/47104

EU PAS number

EUPAS43258

Study ID

47104

DARWIN EU® study

No

Study countries

☐ United Kingdom

☐ United States

Study description

The study will be conducted using validated research-acceptable healthcare data sources to investigate investigates the real-world incidence of major adverse CV outcomes and GI perforation in patients receiving chronic opioid therapy and who have newly initiated naldemedine for OIC (naldemedine cohort), or who are newly prescribed a non-OTC and non-PAMORA medication for OIC with no evidence of prior prescribing (or dispensing) of any PAMORA (reference cohort).

Study status

Planned

Research institutions and networks

Institutions

United BioSource Corporation (UBC)

☐ Switzerland

First published: 25/04/2013

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Institution | **Non-Pharmaceutical company** | **ENCePP partner**

Contact details

Study institution contact

Irene Cosmatos

Study contact

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Primary lead investigator

Irene Cosmatos

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 15/03/2021

Actual: 15/03/2021

Study start date

Planned: 30/12/2021

Data analysis start date

Planned: 31/03/2028

Date of interim report, if expected

Planned: 31/12/2022

Date of final study report

Planned: 29/12/2028

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Shionogi BV

Regulatory

Was the study required by a regulatory body?

Yes

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

EU RMP category 3 (required)

Methodological aspects

Study type

Study type list

Study type:

Non-interventional study

Scope of the study:

Assessment of risk minimisation measure implementation or effectiveness

Main study objective:

Assess the incidence of major adverse cardiovascular (CV) outcomes (a composite of CV death, fatal and nonfatal myocardial infarction MI, and fatal

and nonfatal stroke) and gastrointestinal (GI) perforation in patients initiating naldemedine vs. non-over-the-counter (non-OTC), non-PAMORA prescription treatment for OIC

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

Anatomical Therapeutic Chemical (ATC) code

(A06AH05) naldemedine

naldemedine

Medical condition to be studied

Constipation

Population studied

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)

Estimated number of subjects

26568

Study design details

Outcomes

Characterise the safety profile of patients initiating naldemedine vs. non-OTC, non- PAMORA prescription treatments for OIC in subpopulations under-represented in the clinical development programmes ((with severe hepatic impairment, with a previous history of CV disease, >=75 years old, pregnant women, with severe renal impairment, taking concurrent methadone, treated >1 year. assess the incidence of less severe outcomes in patients initiating naldemedine vs. non-OTC, non-PAMORA prescribed medication for OIC: less severe CV outcomes (hypertension, angina, arrhythmia and syncope), abdominal pain, diarrhoea, vomiting, opioid withdrawal syndrome, anti-analgesic effect due to centrally-mediated opioid receptor antagonism.

Data analysis plan

Poisson regression model will be used to estimate the Relative Risk (RR) and construct 95% CIs of cumulative incidence and exposure-adjusted incidence rate of MACE for each data source. Meta-analysis techniques will be used to summarise primary and secondary endpoints across databases.

Data management

Data sources

Data source(s)

Clinical Practice Research Datalink

Data source(s), other

CPRD

Data sources (types)

Administrative healthcare records (e.g., claims)

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