An Observational Post-Authorization Safety Study (PASS) of MOVENTIG® (Naloxegol) Drug Utilization in Selected European Populations

First published: 03/03/2016

Last updated: 02/07/2024

Study Finalised

Administrative details

EU PAS number

EUPAS12598

Study ID

17818

DARWIN EU® study

No

Study countries

Germany

Norway

Sweden

United Kingdom

Study description

This is a drug utilization study that uses observational data from multiple countries. The study utilizes a retrospective new users cohort (patients newly prescribed naloxegol) study design in each of the countries.

Study status

Finalised

Research institutions and networks

Institutions

PPD Evidera

Sweden

United Kingdom

United States

First published: 20/11/2013

Last updated: 22/09/2025

Institution **Laboratory/Research/Testing facility** **Non-Pharmaceutical company** **ENCePP partner**

PPD Evidera

Sweden

United Kingdom

United States

First published: 20/11/2013

Last updated: 22/09/2025

Institution | Laboratory/Research/Testing facility | Non-Pharmaceutical company | ENCePP partner

IQVIA

United Kingdom

First published: 12/11/2021

Last updated: 22/04/2024

Institution | Non-Pharmaceutical company | ENCePP partner

IMS Health

First published: 01/02/2024

Last updated: 01/02/2024

Institution

Contact details

Study institution contact

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Study contact

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Primary lead investigator

Javier Cid

Primary lead investigator

Study timelines

Date when funding contract was signed
Actual: 13/10/2015

Study start date
Actual: 01/12/2015

Date of final study report
Actual: 15/07/2021

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Kyowa Kirin

Study protocol

D3820R00006 CSP - PRAC 01212015 final.pdf (331.4 KB)

D3820R00006 CSP - PRAC 01212015 final_ppd OK.pdf (335.3 KB)

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 topic:

Human medicinal product

Study type:

Non-interventional study

Scope of the study:

Drug utilisation

Data collection methods:

Secondary use of data

Main study objective:

-To describe the characteristics of patients prescribed naloxegol at time of first prescription (demographics, targeted comorbidities, targeted comedications, provider characteristics, indication characteristics). -To describe any of the following treatment patterns: Discontinuation, Switching, Augmentation, Restart the prescription of naloxegol after temporary discontinuation, Change in dosing

Study Design

Non-interventional study design

Cohort

Other

Non-interventional study design, other

Retrospective study

Study drug and medical condition

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

NALOXEGOL

Population studied

Short description of the study population

The study population included new users of naloxegol (individuals newly prescribed naloxegol) in real-world practice reported from the selected European countries.

Inclusion criteria:

1. The patient has at least 1 prescription of naloxegol in his/her medical record anytime during the study period.
2. The patient has at least 12 months of computerized records prior to the first prescription of naloxegol (index date).

Exclusion criteria

No exclusion criteria will be applied.

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

Hepatic impaired

Pregnant women

Renal impaired

Estimated number of subjects

17.254

Study design details

Outcomes

Treatment outcomes: - Discontinuation: no prescription of naloxegol in the period of twice the number of days of supply of the last prescription following

its expiry date - Switching from naloxegol to other drug(s) potentially used by patients with opioid induced constipation (OIC) - Augmentation with other drugs potentially used by patients with OIC - Restart after temporary discontinuation

Data analysis plan

All analyses for this study are descriptive and performed in each of the study countries separately, and if possible overall for all patients combined. Summary statistics (ie, mean, standard deviation, median, minimum, and maximum) are presented for continuous variables and number and proportion/percentage are presented for categorical ones. The number and proportion of patients with missing data are reported for each of the variables of interest. The 95% confidence interval (CI) for the proportion of patients having a specific characteristic are presented using the Wilson Score method. Time to events are described using estimates (eg, median) and 95% CI based on the Kaplan-Meier method. Sensitivity analyses are conducted by also describing treatment discontinuation considering a shorter allowable gap. Exploratory analyses of potential predictors of length of naloxegol use are conducted using appropriate methodology (eg, Cox regression analysis)

Documents

Study results

Naloxegol DU Report_Final_V1.0_clean_15July2021_Abstract.pdf (517.48 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 source(s)

Sweden National Prescribed Drugs Register / Läkemedelsregistret

THIN® (The Health Improvement Network®)

Data source(s), other

NorPD

Data sources (types)

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