

# An Observational Post-Authorization Safety Study (PASS) of MOVENTIG® (Naloxegol) Among Patients Aged 18 Years and Older Treated with Opioids Chronically

**First published:** 04/03/2016

**Last updated:** 02/07/2024

Study

Finalised

## Administrative details

### EU PAS number

EUPAS12669

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### Study ID

17821

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### DARWIN EU® study

No

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### Study countries

 Netherlands

 United Kingdom

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## Study description

This study is designed to provide additional data to characterize the safety of naloxegol in the indicated population and within at risk vulnerable populations identified in the naloxegol RMP by describing type and frequency of identified and potential risks (including bowel perforation, acute myocardial infarction, stroke, cardiovascular-specific mortality, all-cause mortality, hypertension, opioid withdrawal, abdominal pain, diarrhea, syncope, and change in pain severity) in patients  $\geq 18$  years of age who were treated with opioids chronically and subsequently treated with naloxegol in routine post-authorization use.

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## 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

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## The PHARMO Institute for Drug Outcomes Research (PHARMO Institute)

 Netherlands

**First published:** 07/01/2022

**Last updated:** 19/12/2025

**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

[javier.cid@evidera.com](mailto:javier.cid@evidera.com)

### Primary lead investigator

Javier Cid

Primary lead investigator

## Study timelines

### Date when funding contract was signed

Actual: 13/10/2015

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### Study start date

Actual: 01/12/2015

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### Date of final study report

Planned: 15/12/2023

Actual: 02/12/2022

## Sources of funding

- Pharmaceutical company and other private sector

## More details on funding

Kyowa Kirin

## Study protocol

[D3820R00009 CSP - PRAC 07312015 final.pdf](#) (418.76 KB)

[m1-8-2 D3820R00009 PASS CSP\\_v6.1\\_29Mar2021.pdf](#) (1.25 MB)

## Regulatory

### **Was the study required by a regulatory body?**

Yes

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

EU RMP category 3 (required)

## Methodological aspects

### Study type

### Study type list

#### **Study topic:**

Disease /health condition

Human medicinal product

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#### **Study type:**

Non-interventional study

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**Scope of the study:**

Assessment of risk minimisation measure implementation or effectiveness

Safety study (incl. comparative)

**Data collection methods:**

Secondary use of data

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**Main study objective:**

To assess the incidence of bowel perforation, acute MI, stroke, all-cause mortality, and hypertension in patients treated with naloxegol, a concurrent reference cohort, and by subpopulations (patients aged  $\geq 65$  years, or pregnant, or with prior cardiovascular risk, or with prior renal or hepatic impairment, or with concurrent methadone use or use of CYP3A inhibitors/inducers or P-gP modulators)

## Study Design

**Non-interventional study design**

Cohort

Other

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**Non-interventional study design, other**

Retrospective study

## Study drug and medical condition

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

NALOXEGOL

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## **Medical condition to be studied**

Large intestine perforation  
Small intestinal perforation  
Acute myocardial infarction  
Cerebral infarction  
Cerebellar infarction  
Cerebrovascular accident  
Cerebral haemorrhage  
Cerebellar haemorrhage  
Death  
Hypertension

## **Population studied**

### **Short description of the study population**

The study focused on patients from the UK, Germany, and the Netherlands who receive naloxegol prescriptions. Patients aged 18 and above, with at least one year of continuous data, and exposure to regular opioid use, will be included in the National Institute of Addiction and Metabolism (NIC). Patients with non-PAMORA laxative prescriptions will be included in the Clinical Research Centre (CRC). Patients will be grouped by cancer or non-cancer for analysis.

Inclusion criteria:

1. Patient receives a new prescription for naloxegol or a non-PAMORA laxative (Note: only non-PAMORA laxatives that are approved/marketed in the EU at the time naloxegol is authorised are permitted).

Patients will be excluded from either the NIC or CRC if they meet any of the following criteria:

1. Patients < 18 years of age on cohort entry date.

2. Patients with < 1 year of continuous data available prior to cohort entry date.
  3. Patients without exposure to current regular opioid use (current regular opioid use defined by > 302 days of opioid exposure within the 180 days prior to and inclusive of the cohort entry date).
  4. Exposure to PAMORA laxatives, alvimopan, methylnaltrexone, or naloxone + opioid combination (including fixed-dose combinations) prior to cohort entry date.
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### **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)
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### **Estimated number of subjects**

10000

## **Study design details**

### **Outcomes**

Bowel perforation, acute MI, stroke, all-cause mortality, and hypertension. CV-specific mortality, opioid withdrawal, abdominal pain, diarrhea, syncope, and change in pain severity

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### **Data analysis plan**

Demographic, clinical, and treatment characteristics in the patients' medical history for the naloxegol inception cohort and concurrent reference cohort overall and within sub-populations of interest are described. Incidence proportion and exposure-adjusted incidence rates for pre-specified health

outcomes of interest, and their 95% confidence interval, are reported, by presence or absence of cancer. Incidence proportion is the number of patients with the outcome divided by the total number of patients. Exposure-adjusted incidence rate is the number of first occurrences of each health outcome divided by the total aggregate person-time accrued by all patients in that exposure group. The 95% CI were calculated based on the Wilson Score method. Sensitivity analyses were not conducted due to early termination of the study. Empirical time-to-event curves were derived for time to each of outcomes of interest. The Kaplan-Meier method was used to ascertain the shape of the distributions.

## Documents

### Study results

[Naloxegol\\_SES\\_final report\\_2022\\_V1.0\\_Abstract.pdf](#) (595.05 KB)

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## 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)**

PHARMO Data Network

THIN® (The Health Improvement Network®)

German Pharmacoepidemiological Research Database

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## **Data sources (types)**

[Administrative healthcare records \(e.g., claims\)](#)

[Disease registry](#)

[Drug dispensing/prescription data](#)

[Electronic healthcare records \(EHR\)](#)

# Use of a Common Data Model (CDM)

## **CDM mapping**

No

# Data quality specifications

## **Check conformance**

Unknown

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## **Check completeness**

Unknown

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## **Check stability**

Unknown

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## **Check logical consistency**

Unknown

# Data characterisation

## **Data characterisation conducted**

No