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

PURI
https://redirect.ema.europa.eu/resource/17818

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 institution and networks

Institutions

Evidera

United Kingdom
First published: 20/11/2013
Last updated 07/03/2024

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

Evidera

United Kingdom
First published: 20/11/2013
Last updated 07/03/2024

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

IQVIA

United Kingdom
First published: 12/11/2021
Last updated 22/04/2024

Institution
ENCePP partner
Non-Pharmaceutical company

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 data collection

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
17254

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

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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

Data sources

Data source(s)
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