United States Post-Marketing Observational Cardiovascular Safety Study in Patients taking Naloxegol (Naloxegol US Post-Market Requirement CV Safety)

First published: 16/03/2017

Last updated: 14/03/2024

Study Ongoing

Administrative details

EU PAS number

EUPAS18201

Study ID

25981

DARWIN EU® study

No

Study countries

United States

Study description

The overall research goal for this study is to provide additional data to characterize the safety of naloxegol in patients aged 18 years and older who do not have a diagnosis of cancer and who are treated with opioids chronically.

Study status

Ongoing

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**

HealthCore

First published: 01/02/2024

Last updated: 01/02/2024

Institution

HealthCore United States, Edward Hines Jr. VA Hospital United States, Chicago Association for Research and Education in Science United States, Scott & White Memorial Hospital United States

Contact details

Study institution contact

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Study contact

SLane@Valinorrx.com

Primary lead investigator

Eric Wittbrodt

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 13/10/2015

Actual: 13/10/2015

Study start date

Planned: 01/12/2015

Actual: 01/12/2015

Data analysis start date
Planned: 01/06/2016

Actual: 01/06/2016

Date of interim report, if expected
Planned: 30/06/2018

Actual: 23/05/2018

Date of final study report
Planned: 31/12/2023

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

AstraZeneca

Study protocol

D3820R00008-clinical-study-protocol-25Sep2015 Redacted.pdf (465.99 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)

Other study registration identification numbers and links

D3820R00008

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:

To assess the relative risk of MACE among naloxegol-treated patients compared with that among patients on prescription non-PAMORA OIC treatment.

Study Design

Non-interventional study design

Cohort

Case-control

Other

Non-interventional study design, other

Self-controlled case series

Study drug and medical condition

Medicinal product name, other

Moventik

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

4.400

Study design details

Outcomes

MACE defined as a composite of myocardial infarction, stroke and cardiovascular death, Individual components of MACE

Data analysis plan

The primary effect estimate is the relative incidence of MACE during naloxegol exposure as compared to during comparison drug treatment. The analysis of MACE is based on the Cox proportional hazards model with an indicator for naloxegol versus comparison drug treatment as a predictor, a non-specified baseline hazard with stratification by calendar year of cohort entry, and decile of propensity score. In addition to treatment status, the predictors will include covariates that are not balanced by the propensity scores.

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)

Electronic healthcare records (EHR)

Other

Data sources (types), other

National Death Index

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