# 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

**PURI**

https://redirect.ema.europa.eu/resource/25981

**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

### Evidera

United Kingdom

**First published:** 20/11/2013

**Last updated:** 07/03/2024

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**

Eric Wittbrodt

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

**Name of medicine, 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**

4400

## 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

## 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