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 institution 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
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Study contact

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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 data (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