Use of Nalmefene (Selincro®) in European databases: Cohort design using longitudinal electronic medical records or claims databases

First published: 27/07/2016

Last updated: 20/02/2024

Study Ongoing

Administrative details

EU PAS number

EUPAS14083

Study ID

16907

DARWIN EU® study

No

Study countries

- ☐ Germany
- ☐ Sweden
- ☐ United Kingdom

Study description

Databases analyses in several European countries have been proposed to investigate patterns of use of Selincro® in real clinical practice taking into account the important risks and missing information documented in the RMP.

Study status

Ongoing

Research institutions and networks

Institutions

H. Lundbeck

First published: 01/02/2024

Last updated: 01/02/2024

Institution

Contact details

Study institution contact

Email contact via H. Lundbeck A/S Email contact via H. Lundbeck A/S LundbeckClinicalTrials@lundbeck.com

Study contact

LundbeckClinicalTrials@lundbeck.com

Primary lead investigator

Email contact via H. Lundbeck A/S Email contact via H. Lundbeck A/S

Primary lead investigator

Study timelines

Date when funding contract was signed
Planned: 15/11/2013

Actual: 15/07/2013

Study start date
Planned: 01/08/2016

Actual: 01/08/2016

Data analysis start date
Planned: 02/08/2016

Actual: 02/08/2016

Date of interim report, if expected
Planned: 31/07/2017

Date of final study report
Planned: 28/06/2019

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

H. Lundbeck A/S

Study protocol

15649A version 3 0 09 MAR 2015 Abstract for Encepp .pdf(41.79 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 type:

Non-interventional study

Scope of the study:

Drug utilisation

Main study objective:

The primary objective of the database analysis is to describe the use of Selincro® in clinical practice, particularly in different sub-populations.

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

Medical condition to be studied

Alcohol use

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

2000

Study design details

Outcomes

age, gender,pregnancy, proportion of patients with increased (>3xULN) ALAT or ASAT, proportion of patients with psychiatric or somatic comorbidity, proportion of patients with history of seizure, the proportion of patients with concurrent prescription of CNS active medication, The use of Selincro® over more than one year and the occurrence of overdose.The use of Selincro® in patients outside the indication defined in the SmPC.

Data analysis plan

In this non comparative study, only descriptive statistics will be used. Consequently, all variables will be summarised using descriptive techniques: summary statistics (mean, standard deviation, median, inter-quartile range, minimum and maximum values) will be presented for continuous variables, and countsand percentages will be presented for categorical and binary variables. Missing values will be displayed.

Data management

Data sources

Data source(s)

Clinical Practice Research Datalink

Sweden National Prescribed Drugs Register / Läkemedelsregistret

---

Data sources (types)

Administrative healthcare records (e.g., claims)

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