Non-interventional multi-country prospective cohort study to investigate patterns of use of Selincro® and frequency of adverse drug reactions in routine clinical practice (START)

First published: 27/06/2014

Last updated: 20/02/2024

Study Ongoing

Administrative details

EU PAS number

EUPAS5678

Study ID

16904

DARWIN EU® study

No

Study countries

- ☐ Czechia
- ☐ Denmark

- [ ] France
- [ ] Germany
- [ ] Greece
- [ ] Italy
- [ ] Poland
- [ ] Portugal
- [ ] Romania
- [ ] Sweden
- [ ] United Kingdom

Study description

The aim of this study is to investigate patterns of use of Selincro® and frequency of adverse drug reactions in routine clinical practice

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: 03/06/2013

Actual: 03/06/2013

Study start date

Planned: 30/06/2014

Actual: 28/08/2014

Data analysis start date

Planned: 30/06/2016

Actual: 25/07/2016

Date of interim report, if expected

Planned: 30/12/2016

Actual: 12/12/2016

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

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

Safety study (incl. comparative)

Main study objective:

- Patterns of use of Selincro® in routine clinical practice,- Frequency of adverse drug reactions of special interest inpatients treated with Selincro® in routine clinical practice in theentire study population and in the subpopulations of interest.

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

Characteristics at initiation of Selincro®: socio-demographics, % with alcohol dependence diagnosis, psychiatric comorbidities or somatic comorbidities, % with increased ALAT/ASAT (>3ULN, if available), % with psychosocial support, % with CNS-active medicines and opioids, pregnancy and lactation, off-label use. Patterns of use overall and by sub-group.Occurrence of adverse drug reactions, overall and by sub-group.

Data analysis plan

In this non-comparative cohort study, all data analyses will be purely descriptive and no statistical testing will be performed as the primary study objectives are to investigate the patterns of use of Selincro® and the frequency of ADRs of special interest in patients treated with Selincro® in routine clinical practice in the entire study population and in the subpopulations of interest.These descriptive analyses will be conducted in the entire study population and in the subpopulations of interest (if relevant), and by country.Summary statistics (mean, standard deviation SD, median, interquartile range IQR, minimum, and maximum values) will be presented for continuous variables and counts and, if relevant, percentages will be presented for categorical and binary variables.

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)

Other

Data sources (types), other

Prospective patient-based data collection

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