# 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:** 09/10/2025

Study | Finalised

## 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**

Finalised

# Research institutions and networks

## Institutions

### H. Lundbeck

**First published:** 01/02/2024

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**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

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**Study start date**

Planned: 30/06/2014

Actual: 28/08/2014

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**Data analysis start date**

Planned: 30/06/2016

Actual: 25/07/2016

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**Date of interim report, if expected**

Planned: 30/12/2016

Actual: 12/12/2016

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

Actual: 19/06/2019

## 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 topic:**

Human medicinal product

**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

**Medicinal product name**

SELINCRO

**Study drug International non-proprietary name (INN) or common name**

NALMEFENE

**Anatomical Therapeutic Chemical (ATC) code**

(N07BB05) nalmefene

nalmefene

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**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)

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**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.

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**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.

## Documents

**Study publications**

Safety and Persistence of Nalmefene Treatment for Alcohol Dependence. Results f…

# 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