

# Non-interventional Cohort Study to Investigate Sertindole Prescription Management in Real-Life Practice

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Study

Finalised

## Administrative details

### EU PAS number

EUPAS14033

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### Study ID

22800

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### DARWIN EU® study

No

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### Study countries

- Denmark
- Finland
- Greece
- Poland

Slovakia

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### Study description

The objective of the study is to check compliance of sertindole prescribers to perform ECG monitoring in real-life practice in line with sertindole SmPC requirement.

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### Study status

Finalised

## Research institutions and networks

### Institutions

[H. Lundbeck](#)

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

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Institution

[TFS Lünd \(Sweden\)](#)

## Contact details

### Study institution contact

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H.Lundbeck A/S LundbeckClinicalTrials@lundbeck.com

Study contact

[LundbeckClinicalTrials@lundbeck.com](mailto: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: 18/07/2016

Actual: 18/07/2017

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### **Study start date**

Planned: 30/12/2016

Actual: 12/12/2016

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### **Data analysis start date**

Planned: 28/02/2017

Actual: 27/10/2017

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### **Date of final study report**

Planned: 29/12/2017

Actual: 19/12/2017

## Sources of funding

- Pharmaceutical company and other private sector

## More details on funding

H.Lundbeck A/S

## Study protocol

[14290A Protocol Asbtract Edition 3.1.pdf](#) (100.92 KB)

## Regulatory

### **Was the study required by a regulatory body?**

Yes

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### **Is the study required by a Risk Management Plan (RMP)?**

EU RMP category 3 (required)

## Methodological aspects

### Study type

### Study type list

#### **Study topic:**

Disease /health condition

Human medicinal product

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**Study type:**

Non-interventional study

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**Scope of the study:**

Assessment of risk minimisation measure implementation or effectiveness

**Data collection methods:**

Secondary use of data

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**Main study objective:**

The objective of the study is to check compliance of sertindole prescribers to perform ECG monitoring in real-life practice in line with sertindole SmPC requirement.

## Study Design

**Non-interventional study design**

Cohort

## Study drug and medical condition

**Medicinal product name, other**

SERDOLECT

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**Medical condition to be studied**

Schizophrenia

## Population studied

## **Short description of the study population**

Patients who received at least one prescription of sertindole recruited by psychiatrists from in- or outpatient clinics from 3 countries in order to represent different geographic regions of Europe where sertindole is being marketed: Denmark representing Northern Europe, Greece representing South-Eastern Europe and Poland representing Central Europe.

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## **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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## **Special population of interest**

Other

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## **Special population of interest, other**

Schizophrenia patients

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## **Estimated number of subjects**

150

# Study design details

## **Outcomes**

The number and percentage of patients with an ECG performed will be presented at different timepoints/events (as listed in the SmpC).

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## Data analysis plan

All assessment data will be summarised by time point and country using descriptive techniques. Unless otherwise specified, summary statistics (n, mean, standard deviation, median, 1st and 3rd quartiles, minimum and maximum values) will be presented for continuous variables. 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](#)

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### Data sources (types), other

Field study with secondary data collection from investigator's medical records (medical chart review)

## Use of a Common Data Model (CDM)

### CDM mapping

No

## Data quality specifications

### **Check conformance**

Unknown

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### **Check completeness**

Unknown

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### **Check stability**

Unknown

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### **Check logical consistency**

Unknown

## Data characterisation

### **Data characterisation conducted**

Unknown