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

First published: 01/09/2016

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Study Finalised

Administrative details

EU PAS number

EUPAS14033

Study ID

22800

DARWIN EU® study

No

Study countries

- ☐ Denmark
- ☐ Finland
- ☐ Greece
- ☐ Poland

Slovakia

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.

Study status

Finalised

Research institutions and networks

Institutions

H. Lundbeck

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Institution

TFS Lünd (Sweden)

Contact details

Study institution contact

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Study contact

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Primary lead investigator

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Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 18/07/2016

Actual: 18/07/2017

Study start date

Planned: 30/12/2016

Actual: 12/12/2016

Data analysis start date

Planned: 28/02/2017

Actual: 27/10/2017

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

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

Study type:

Non-interventional study

Scope of the study:

Assessment of risk minimisation measure implementation or effectiveness

Data collection methods:

Secondary use of data

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

Name of medicine, other

SERDOLECT

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.

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)

Special population of interest

Other

Special population of interest, other

Schizophrenia patients

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).

Data analysis plan

All assessment data will be summarised by time point and country usingdescriptive 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

Data sources

Data sources (types)

Other

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

Check completeness

Unknown

Check stability

Unknown

Check logical consistency

Unknown

Data characterisation

Data characterisation conducted

Unknown