A non-interventional post-authorisation safety study (PASS) of vortioxetine in Europe

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Study Ongoing

Administrative details

PURI

https://redirect.ema.europa.eu/resource/26753

EU PAS number

EUPAS19199

Study ID

26753

DARWIN EU® study

No

Study countries

☐ Finland

☐ Netherlands

☐ Spain

Study description

This post-authorisation safety study (PASS) will be conducted using longitudinal automatic healthcare databases. It uses a non-comparative historical cohort design to explore:- the patterns of use of vortioxetine in some populations or situations considered as important missing information- the frequency of occurrence of selected important potential risks (suicidal behaviours, convulsions/seizures and severe renal or hepatic events potentially due to precipitation of metabolites in kidney and liver).- the frequency of events of abuse/dependence for exploratory detection of potential signals, in relation with the important missing information Abuse/Dependence within “Misuse for Illegal Purposes”- withdrawal due to lack of efficacy in patients aged 75 and over, in relation with the important missing information “Patients Aged 75 and Over”.All incident vortioxetine users during the study period (between market entry date and end of study period) will be included. Study period will be the time it takes for the adequate sample size (N=2000 per database) to be reached. Descriptive statistics will be used to estimate the proportion of patients with pre-defined charcateristics (e.g. Proportion of incident users without any diagnostic codes for depression near the index date), as well as the incidence rates of certain pre-defined events (e.g. the incidence rate of events related to suicidal behaviours).

Study status

Ongoing

Research institutions and networks

Institutions

H. Lundbeck

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Institution

Contact details

Study institution contact

Non-interventional Research Manager H. Lundbeck A/S

Study contact

LundbeckClinicalTrials@lundbeck.com

Primary lead investigator

Non-interventional Research Manager H. Lundbeck A/S

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 19/08/2014

Actual: 19/08/2014

Study start date

Planned: 01/06/2017

Actual: 01/06/2017

Data analysis start date
Actual: 15/06/2017

Date of final study report
Planned: 31/12/2021

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

H. Lundbeck A/S

Study protocol

16034N Master Protocol v2.0 Abstract.pdf(247.76 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:

Assessment of risk minimisation measure implementation or effectiveness

Drug utilisation

Main study objective:

Aims of this study are to explore: the patterns of use of vortioxetine in some populations or situations considered as important missing information, the frequency of occurrence of selected important potential risks, the frequency of events of abuse/dependence, withdrawal due to lack of efficacy in patients aged 75 and over.

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

Name of medicine

BRINTELLIX

Medical condition to be studied

Major depression

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)

Special population of interest

Hepatic impaired

Pregnant women

Renal impaired

Estimated number of subjects

6000

Study design details

Data analysis plan

In this non-comparative study, descriptive statistics will be used. Summary statistics (mean, standard deviation, median, inter-quartile range, minimum and maximum values) will be presented for continuous variables. Counts and percentages will be presented for categorical and binary variables. In addition, incidence rates (number of events divided by person-time at risk) will be calculated for selected events.

Data management

Data sources

Data source(s)

PHARMO Data Network

Data sources (types)

Administrative healthcare records (e.g., claims)

Drug dispensing/prescription data

Electronic healthcare records (EHR)

Other

Data sources (types), other

Population-based registers

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