Characterising the safety profile of lurasidone in clinical practice: A drug utilisatio and safety study using a United Kingdom primary care database

First published: 07/04/2017

Last updated: 15/03/2024

Study Planned

Administrative details

PURI

https://redirect.ema.europa.eu/resource/18537

EU PAS number

EUPAS18536

Study ID

18537

DARWIN EU® study

No

Study countries

United Kingdom

Study description

The study will describe drug utilization patters and characterize the safety profile of lurasidone compared to other second generation antipsychotics in a real world UK primary healthcare setting

Study status

Planned

Research institutions and networks

Institutions

OXON Epidemiology

Spain

United Kingdom

First published: 06/12/2010

Last updated: 15/03/2024

Institution | Laboratory/Research/Testing facility | Non-Pharmaceutical company | ENCePP partner

Contact details

Study institution contact

Quentin Clarke

Study contact

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Primary lead investigator

Nawab Qizilbash MBChB MRCP(UK) BSc MSc DPhil(Oxon.)

Primary lead investigator

Study timelines

Date when funding contract was signed
Actual: 14/01/2014

Study start date
Planned: 01/06/2017

Date of final study report
Planned: 01/12/2021

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Sunovion Pharmaceuticals Europe Ltd

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:

The overall aim of this research is to characterise the safety profile of lurasidone compared other second generation antipsychotics in clinical practice

Study Design

Non-interventional study design

Cross-sectional

Study drug and medical condition

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

LURASIDONE

Medical condition to be studied

Schizophrenia

Population studied

Age groups

Children (2 to < 12 years)

Adolescents (12 to < 18 years)

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

6611

Study design details

Data analysis plan

Drug Utilisation Study: Descriptive statistics, including means (SD) and medians (10th to 90th percentiles) for continuous variables, and numbers and percentages for categorical variables will be used to examine the following characteristics in new users of lurasidone compared with all other second generation antipsychotic drugs combined: demographics, comorbidities and comedications, pattern of onset, dose adjustment, and duration of therapy, prevalence ofa schizophrenia diagnosis, and prevalence of other relevant psychiatric indications in the absence of a schizophrenia diagnosis. Numbers of patients censored from the study by calendar year, and length of follow-up by year of therapy initiation will be reported.PASS: Exposure propensity scores will be used to frequency match new users of lurasidone with new users of comparator second generation antipsychotics. Patients will also be matched on age and gender.

Data management

Data sources

Data sources (types)

Electronic healthcare records (EHR)

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