Evaluation of the safety profile of lurasidone: a post-authorization safety study using United States administrative claims databases (Lurasidone PASS program)

First published: 05/03/2020

Last updated: 04/04/2024

Study Ongoing

Administrative details

EU PAS number

EUPAS34004

Study ID

40822

DARWIN EU® study

No

Study countries

☐ United States

Study description

The aim of this PASS study is to evaluate the safety profile of lurasidone for treatment of schizophrenia in a real-world setting. The primary objective is to compare the incidence of important identified risks and important potential risks in patients treated with lurasidone to patients treated with other second generation oral atypical antipsychotics (OAAs).

Study status

Ongoing

Research institutions and networks

Institutions

Angelini Pharma

First published: 01/02/2024

Last updated: 01/02/2024

Institution

Contact details

Study institution contact

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Study contact

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Primary lead investigator

Fabrizio Calisti

Primary lead investigator

Study timelines

Date when funding contract was signed
Actual: 13/12/2019

Study start date
Actual: 05/03/2020

Date of final study report
Planned: 30/12/2020

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Angelini Pharma SpA

Regulatory

Was the study required by a regulatory body?

No

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

EU RMP category 3 (required)

Methodological aspects

Study type:

Non-interventional study

Scope of the study:

Assessment of risk minimisation measure implementation or effectiveness

Drug utilisation

Main study objective:

The primary objective is to compare the incidence of important identified risks and important potential risks in patients treated with lurasidone to patients treated with other second generation oral atypical antipsychotics (OAAs).

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

Medicinal product name

LATUDA

Medical condition to be studied

Schizophrenia

Population studied

Age groups

- 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)

Estimated number of subjects

6611

Study design details

Outcomes

The primary outcomes include important risks to patients receiving OAAs, and those risks can be regarded as identified or potential

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Data analysis plan

The primary analyses will include:• Patient attrition• Descriptive statistics on the demographics and clinical characteristics of the two study cohorts • The number and percent of patients exposed to lurasidone and other OAAs• The number and percent of patients experiencing the outcomes of interest among the two study cohortsAnalyses will be conducted overall and for the subgroups specified.

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.

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