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

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Last updated: 03/06/2026

Study Planned

Administrative details

EU PAS number

EUPAS18536

Study ID

18537

DARWIN EU® study

No

Study countries

United Kingdom

Study description

The study aims to describe drug utilisation patterns and characterise the safety profile of lurasidone compared with other second-generation antipsychotics in a real-world UK primary care setting

Study status

Planned

Research institutions and networks

Institutions

OXON Epidemiology

Spain

United Kingdom

First published: 06/12/2010

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

Contact details

Study institution contact

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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 topic:

Human medicinal product

Study type:

Non-interventional study

Scope of the study:

Drug utilisation

Safety study (incl. comparative)

Data collection methods:

Secondary use of data

Main study objective:

The overall aim of this research was to characterise the safety profile of lurasidone compared with 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

Anatomical Therapeutic Chemical (ATC) code

(N05AE05) lurasidone

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

Setting

Primary care database

Data analysis plan

Drug Utilisation Study: Descriptive statistics, including means (SDs) and medians (10th–90th percentiles) for continuous variables, and frequencies and percentages for categorical variables, were used to examine the following characteristics among new users of lurasidone compared with new users of all other second-generation antipsychotics combined: demographics, comorbidities and concomitant medications, treatment initiation patterns, dose adjustments, duration of therapy, prevalence of schizophrenia diagnoses, and prevalence of other relevant psychiatric indications in the absence of a schizophrenia diagnosis. The number of patients censored during follow-up, by calendar year, and the duration of follow-up, by year of treatment initiation, were also reported.

Post-Authorisation Safety Study (PASS): Exposure propensity scores were used to frequency-match new users of lurasidone with new users of comparator second-generation antipsychotics. Patients were additionally matched on age and sex.

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)

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