An observational, real world evidence study to describe clinical experience with lurasidone in the treatment of adult patients with schizophrenia in routine clinical practice in Europe (LATUDA)

First published: 22/03/2019

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Study Finalised

Administrative details

EU PAS number

EUPAS28735

Study ID

46673

DARWIN EU® study

No

Study countries

Netherlands

Switzerland

United Kingdom

Study description

This is an international, multi-centre observational, real world evidence study. This study will be conducted in 4 to 8 mental health centres in the United Kingdom (UK), Netherlands and Switzerland. The study is based on both retrospective and prospective collection of data from patients' medical records. It is a single group study without a comparator, to reflect real world clinical practice. There will be no changes to patient management for the purposes of any part of the study and no additional tests, investigations or visits will be required. The population for this study is adult patients diagnosed with schizophrenia who received treatment with a medicine called lurasidone as part of their standard clinical care. It is expected to recruit 80 patients in total. The main purpose is to find out more about how lurasidone is used to treat patients with schizophrenia in the real world and how well it works.

Study status

Finalised

Research institutions and networks

Institutions

Multiple centres: 7 centres are involved in the study

Contact details

Study institution contact

Andrew Jones medinfo@cnx-therapeutics.com

Study contact

medinfo@cnx-therapeutics.com

Primary lead investigator

Matthew Sargeant

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 18/10/2017

Actual: 18/10/2017

Study start date

Planned: 04/02/2019

Actual: 12/02/2019

Data analysis start date

Planned: 29/05/2020

Actual: 01/04/2021

Date of final study report

Planned: 31/08/2020

Actual: 06/12/2021

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

CNX Therapeutics Ltd (formerly Sunovion Pharmaceuticals Ltd)

Study protocol

PT-SUNOVION LATUDA Study Protocol V3 0 20SEP18 FINAL.pdf (885.02 KB)

PT_Sunovion LATUDA_v4 0_25OCT19_clean.pdf (504.4 KB)

Regulatory

Was the study required by a regulatory body?

No

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

Not applicable

Other study registration identification numbers and links

NP-LAT-721-18

Methodological aspects

Study type

Study type list

Study topic:

Human medicinal product

Disease /health condition

Study type:

Non-interventional study

Scope of the study:

Disease epidemiology

Drug utilisation

Effectiveness study (incl. comparative)

Data collection methods:

Secondary use of data

Main study objective:

To describe the dose titration process, dosing regimens, treatment duration and reasons for discontinuation following initiation of lurasidone in adult patients with schizophrenia.

Study Design

Non-interventional study design

Cohort

Other

Non-interventional study design, other

Multicentre observational study

Study drug and medical condition

Medicinal product name

LATUDA

Medical condition to be studied

Schizophrenia

Population studied

Short description of the study population

Population with schizophrenia treated with lurasidone in routine clinical practice.

Inclusion criteria

1. Aged ≥18 years of age at time of initiation of lurasidone.
2. Provided consent for access to medical records for study data collection (applicable to living patients only).
3. Documented diagnosis of schizophrenia before the initiation of lurasidone.
4. Initiated on lurasidone after the 1st January 2016.
5. Judged to have capacity by their clinician to provide valid written informed consent to participate in this study.

Exclusion criteria

1. Patients whose medical records were unavailable for review.
2. Patients who participated in a clinical trial of an investigational medicinal product during the post-index observation period.

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

80

Study design details

Outcomes

Summary measures of lurasidone treatment duration i.e. Proportion of patients taking treatment for full 12 months, Summary measures of baseline demographics and clinical characteristics Summary measures of treatment history for schizophrenia Dose distribution of lurasidone prescribed and summary measures of dose regimen Time until first relapse following lurasidone initiation Adverse events following lurasidone initiation Summary measures of healthcare resource utilisation

Data analysis plan

All primary endpoint (and secondary endpoint) analyses will be descriptive in nature. For continuous variables (such as duration of time with disease) the mean, standard deviation, median, interquartile range and range will be calculated. For nominal variables, frequencies and proportions in the form of percentages will be calculated for each group. For investigating changes in

weight, blood glucose, lipid levels and liver function from baseline at 3,6,9 and 12 months following initiation of lurasidone, changes will be described using summary measures as described for continuous variables above for each time, they will then be compared using a paired t-test (or Wilcoxon signed rank test if distributions are non-normal), although based upon a previous study of changes in weight(10) as a result of treatment change, it is expected that any change will be too small to detect a significant change with feasible sample size for the study.

Documents

Study results

CSR_Sunovion LATUDA_v1 0_FINAL.pdf (701.75 KB)

Study, other information

18 LO 1591 250852 Favourable_opinion_12.10.18.pdf (256.47 KB)

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)

Other

Data sources (types), other

Retrospective and prospective collection of data from patients’ medical records

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