An Observational Post-Authorization Safety Surveillance (PASS) Study of SYCREST® (asenapine) among Patients aged 18 and older Diagnosed with Bipolar Disorder (P08307)

First published: 24/05/2017

Last updated: 02/07/2024

Study Finalised

Administrative details

PURI

https://redirect.ema.europa.eu/resource/24619

EU PAS number

EUPAS17631

Study ID

24619

DARWIN EU® study

No

Study countries

☐ United Kingdom

Study description

This is a retrospective cohort study of new-users of asenapine in adult general practice patients in the United Kingdom (UK) from both the Clinical Practice Research Datalink (CPRD) and The Health Improvement Network (THIN) databases to assess incidence rates of identified and potential risks. Comparative analyses will be performed when adequate power is achieved.

Study status

Finalised

Research institutions and networks

Institutions

Merck & Co.

First published: 01/02/2024

Last updated: 01/02/2024

Institution

Contact details

Study institution contact

Clinical Trials Disclosure Merck Sharp & Dohme Corp.

Study contact

datasharing@organon.com

Primary lead investigator

Clinical Trials Disclosure Merck Sharp & Dohme Corp.

Primary lead investigator

Study timelines

Date when funding contract was signed

Actual: 02/12/2010

Study start date

Actual: 01/07/2013

Data analysis start date

Planned: 18/12/2017

Actual: 18/12/2017

Date of interim report, if expected

Actual: 16/09/2014

Date of final study report

Planned: 31/01/2018

Actual: 24/01/2018

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Merck Sharp & Dohme Corp.

Study protocol

8274-110+Protocol_final-redaction.pdf(4.96 MB)

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)

Other study registration identification numbers and links

Merck protocol numbers: P08307, MK-8274-110ClinicalTrials.gov: NCT01495741

Methodological aspects

Study type

Study type list

Study topic:

Disease /health condition

Human medicinal product

Study type:

Non-interventional study

Scope of the study:

Assessment of risk minimisation measure implementation or effectiveness

Data collection methods:

Secondary use of data

Main study objective:

To describe baseline demographic & clinical characteristics, to assess the incidence rates of identified & potential risks in bipolar disorder patients (aged 18+) newly prescribed asenapine, and to compare the incidence rates if adequate study power is achieved for asenapine users relative to two comparison cohorts (risperidone and olanzapine).

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

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

ASENAPINE

Medical condition to be studied

Bipolar disorder

Schizophrenia

Population studied

Short description of the study population

Patients treated with asenapine were identified within the Bipolar Disorder cohort identified from CPRD.

1) First written prescription for asenapine after entry into the Bipolar Disorder cohort or first written prescription for asenapine within 2 years before entry into the Bipolar Disorder cohort (treatment before diagnosis). In CPRD, among patients receiving a prescription of olanzapine and / or risperidone prior to their diagnosis (i.e., patients receiving treatment before diagnosis), the cumulative distribution shows approximately 70% have a duration of time between initiation of treatment and first diagnosis of Bipolar Disorder within 2 years.

2) No use of asenapine within 365 days prior to the first written prescription for asenapine defined above

3) ≥ 365 days of time accumulated between asenapine prescription date and the latter of either (a) the registration date with the general practitioner or (b) the database specific quality indicator date

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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

Patients with schizophrenia, bipolar disorder or any other psychotic disorder

Estimated number of subjects

3000

Study design details

Outcomes

The identified and potential risks among bipolar disorder patients age 18+ prescribed asenapine. The identified risks include extrapyramidal symptoms, somnolence and sedation, neuroleptic malignant syndrome, seizure, hyperprolactinaemia, orthostatic hypotension, allergic reactions, dyslipidaemia and diabetes mellitus. The potential risks include rhabdomyolysis and neutropenia. The same list of identified and potential risks as those in the primary outcomes among patients age 18+ prescribed asenapine for schizophrenia and other diagnoses excluding bipolar disorder.

Data analysis plan

Baseline characteristics will be described for new users of the study drugs of interest.Incidence rates for each risk will be calculated among bipolar disorder patients aged 18+ prescribed asenapine.If pre-specified study power levels are achieved comparison of the identified and potential risks between asenapine and other two comparison cohorts (risperidone and olanzapine) will be

performed.An epidemiology Safety Review Committee comprised of independent clinicians and experts will perform integrated review of the findings of the study, and evaluate the safety data that emerge from the study using both clinical judgment and pre-specified statistical criteria as guidelines.

Documents

Study results

MK-8274-110_final-report_NoAppendices_final-redaction.pdf(2.85 MB)

Data management

Data sources

Data source(s)

THIN® (The Health Improvement Network®)

Clinical Practice Research Datalink

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

Unknown