An Observational Drug Utilization Study of SYCREST® (asenapine) in the United Kingdom (P08308)

First published: 31/05/2017

Last updated: 02/07/2024

Study Finalised

Administrative details

EU PAS number

EUPAS17681

Study ID

24560

DARWIN EU® study

No

Study countries

☐ United Kingdom

Study description

This is a retrospective observational cohort study designed to describe asenapine prescribing patterns in the United Kingdom (UK) during the post-approval period in the general practice (GP) setting. The use of asenapine in Bipolar Disorder (BD) and other indications including Schizophrenia will be described. To provide epidemiological and clinical perspective, use of aripiprazole, olanzapine, quetiapine, and risperidone will also be described.

Study status

Finalised

Research institutions and networks

Institutions

Merck Sharp & Dohme LLC

United States

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Institution | Pharmaceutical company

Contact details

Study institution contact

Clinical Trials Disclosure Merck Sharp & Dohme Corp.
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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: 01/04/2013

Data analysis start date

Planned: 18/12/2017

Actual: 21/12/2017

Date of interim report, if expected

Actual: 13/09/2013

Date of final study report

Planned: 31/01/2018

Actual: 25/01/2018

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Merck Sharp & Dohme Corp

Study protocol

8274-108+Protocol+AM3_final-redaction.pdf(304.77 KB)

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

NCT01498770SCH 900274 P08308MK-8274-108

Methodological aspects

Study type

Study type list

Study topic:

Disease /health condition

Human medicinal product

Study type:

Non-interventional study

Scope of the study:

Drug utilisation

Data collection methods:

Secondary use of data

Main study objective:

1. Describe baseline demographic characteristics, clinical characteristics and healthcare utilization among new users of asenapine aged 18+ years 2. Identify and describe a recent-historical, matched aripiprazole cohort in general practice among patients aged 18+ years, to put asenapine use into context3. Describe off-label use of asenapine in general practice among patients aged 0-17 years

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

Name of medicine

SYCREST

Medical condition to be studied

Bipolar disorder

Schizophrenia

Population studied

Short description of the study population

Patients prescribed asenapine or any other comparator (olanzapine, quetiapine, ziprasidone, iloperidone, risperidone, paliperidone, lurasidone, clozapine, amisulpride, sertindole, zotepine or aripiprazole) as recorded in CPRD UK and meet following criteria-

1) >1 prescription for asenapine or any comparator within the study period

2) Age 18+ at the time the patient receives a prescription for the comparator

3) Date of prescription for asenapine or any comparator occurs after the patient registration date or the database specific quality indicator date

4) A minimum of >365 days of evaluable baseline observation time, occurring prior to the date of prescription for asenapine or any comparator.

Age groups

Infants and toddlers (28 days – 23 months)

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

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

1. Frequency and proportion of use, by psychiatric diagnosis, among new users of asenapine and aripiprazole aged 18+ years in the CPRD and THIN databases2. Frequency and proportion of pediatric use, by psychiatric diagnosis, among asenapine users in the CPRD and THIN databases3. Demographic, clinical characteristics and healthcare utilization among new users of asenapine and aripiprazole

Data analysis plan

All analyses for this drug utilization study will be descriptive. No statistical hypothesis testing will be conducted in this observational study. The frequency and proportions of on- and off-label use will be described.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-8274-108_final-report_NoAppendices_final-redaction.pdf(2.2 MB)

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 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