An Observational Post-Authorization Modified Prescription-Event Monitoring Safety Study To Monitor The Safety And Utilization Of Asenapine (Sycrest) In The Primary Care Setting In England

First published: 11/03/2013

Last updated: 31/03/2024

Study Finalised

Administrative details

EU PAS number

EUPAS3603

Study ID

23506

DARWIN EU® study

No

Study countries

United Kingdom

Study description

Asenapine is a novel atypical antipsychotic agent, developed for the treatment of moderate to severe manic episodes associated with bipolar I disorder and schizophrenia in adults. This post-marketing Modified Prescription-Event Monitoring (M-PEM) safety study of asenapine (SYCREST®) aims to systematically collect and report drug utilisation and safety data on patients newly initiated on treatment with asenapine in the primary care setting in England. The study aims to collect exposure and outcome data for a cohort of approximately 5000 evaluable patients.

Study status

Finalised

Research institutions and networks

Institutions

Drug Safety Research Unit (DSRU)

United Kingdom

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Institution **Not-for-profit** **ENCePP partner**

Contact details

Study institution contact

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Study contact

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Primary lead investigator

Saad Shakir

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 16/08/2011

Actual: 16/08/2011

Study start date

Planned: 01/01/2012

Actual: 01/01/2012

Data analysis start date

Planned: 01/01/2013

Actual: 01/04/2013

Date of final study report

Planned: 28/02/2018

Actual: 12/01/2018

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Merck Inc

Study protocol

Asenapine MPEM protocol_FINAL_August2014.pdf (655.95 KB)

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

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:

Primary data collection

Main study objective:

To study the utilisation and safety of asenapine in (asenapine naïve) new user patients and patients initiated in secondary care with shared care GP prescribing arrangements under normal conditions of use in primary care in England.

Study Design

Non-interventional study design

Other

Non-interventional study design, other

Prescription event monitoring

Study drug and medical condition

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

ASENAPINE MALEATE

Population studied

Short description of the study population

Patients newly initiated on treatment with asenapine in the primary care setting in England.

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)

Estimated number of subjects

5.000

Study design details

Data analysis plan

Data analysis will include: • Hazard rates to explore the incidence of selected events • Descriptive analyses of baseline health profile of patients • Description of the risk profile of events reported in the 12 month observation period in the overall cohort and in patient subgroups of special interest • An assessment of clinical features and management of cases of suicide/ self injury (including overdose) in the cohort exposed to asenapine • Quantification of the incidence of frequently and rarely reported events and to identify previously unrecognised adverse drug reactions (ADRs)

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

Prescription event monitoring

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