An Observational Post-Authorisation Safety Specialist Cohort Monitoring Study (SCEM) to Monitor the Safety and Utilisation of Asenapine (Sycrest) in the Mental Health Trust Setting in England (OBSERVA)

First published: 13/11/2012

Last updated: 02/07/2024

Study Finalised

Administrative details

PURI

https://redirect.ema.europa.eu/resource/28401

EU PAS number

EUPAS3136

Study ID

28401

DARWIN EU® study

No

Study countries

United Kingdom

Study description

A study to evaluate the use and short term safety of Asenapine (Sycrest) in real-life usage in the Mental Health Trust Setting.Asenapine (Sycrest) is a new oral anti-psychotic medication and this study aims to evaluate its use and short term safety when used by patients. The study will be recruiting patients started on asenapine (Sycrest) and asking their care team to answer some simple questions about them at the time they start and again in 12 weeks time. If a participant has an adverse event during that 12 week period, we may ask the patient’s care team to fill out a further follow up questionnaire.No other examinations or tests will be performed. The participant’s consent will be obtained to access their medical records.Any adult patient started by their psychiatric care team on asenapine (Sycrest) during the study period will be eligible to take part. It is a national study covering the whole of EnglandThe study will last for approximately 2 years of data collection (in order to reach a cohort of 1000 patients), although each individual patient will only be involved for a 12 week period of observation.The study is to be carried out independently by the Drug Safety Research Unit (DSRU) in Southampton, although is funded by Merck, the manufacturer of Sycrest.

Study status

Finalised

Research institutions and networks

Institutions

Drug Safety Research Unit (DSRU)

United Kingdom

First published: 10/11/2021

Last updated: 16/02/2024

Institution | Not-for-profit | ENCePP partner

English NHS Mental Health Trusts, Multiple locations in England

Networks

NIHR Medicines for Children Research Network

First published: 01/02/2024

Last updated: 01/02/2024

Network

Contact details

Study institution contact

Elizabeth Lynn

Study contact

elizabeth.lynn@dsru.org

Primary lead investigator

Saad Shakir

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 09/01/2012

Actual: 09/01/2012

Study start date

Planned: 01/11/2012

Actual: 01/11/2012

Date of final study report

Planned: 01/11/2016

Actual: 12/01/2018

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Merck Inc

Study protocol

Asenapine SCEM protocol_ V 18 Final_18_09_2015_clean.pdf(299.92 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)

Methodological aspects

Study type

Study type list

Study topic:

Human medicinal product

Study type:

Non-interventional study

Scope of the study:

Assessment of risk minimisation measure implementation or effectiveness

Drug utilisation

Data collection methods:

Primary data collection

Main study objective:

To monitor the short-term (12 weeks) use and safety of asenapine prescribed to asenapine naïve (new user) patients for the treatment of moderate to severe manic episodes associated with bipolar I disorder, and other psychiatric disorders by psychiatrists under normal conditions of use in the mental health care trust setting.

Study Design

Non-interventional study design

Cohort

Other

Non-interventional study design, other

Intensive monitoring schemes

Study drug and medical condition

Name of medicine

SYCREST

Population studied

Short description of the study population

Patients who present to psychiatrists within the standard course of care as in- or out-patients for treatment of a clinical diagnosis of a mental health disorder which requires pharmacological treatment with an atypical antipsychotic. Patients started on asenapine (Sycrest) were included.

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

1000

Study design details

Outcomes

To provide timely information on:1. Accrual of psychiatrists2. Cohort accrual, the type of clinician responsible for, and the setting of initiation of treatment.3. To quantify the incidence rate of selected important identified and potential risks which are:a) Somnolence and sedation b) Weight gain c) Oral hypoaesthesia d) Swelling of the tongue and throat e) Allergic reactions, 1. To provide timely information on the baseline health profile of patients prescribed asenapine in the mental health care trust and the treatment programme they received 2. To describe the risk profile of events reported in the 12 week observation period in patient subgroups of special interest3. To describe clinical features and management of cases of suicide/ self injury

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Data analysis plan

Data analysis will include• Response rates to describe recruitment• Hazard rates to explore the incidence of selected events• Descriptive analyses of baseline health profile of patients• Analysis of risk and incidence densities to describe the risk profile of events reported in patient subgroups of special interest

Data management

Data sources

Data sources (types)

Other

Data sources (types), other

Prospective patient-based data collection

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