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





### Administrative details

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. As enapine (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

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Network

### 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: 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 inor 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

#### 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

### **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

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