

A cohort study to monitor the safety and use of prolonged-release quetiapine (OASIS)

First published: 20/01/2014

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Study

Finalised

Administrative details

EU PAS number

EUPAS5411


Study ID

20672

DARWIN EU® study

No

Study countries

 United Kingdom

Study description

The study is designed to examine the short-term (up to 12 weeks) safety and use of quetiapine fumarate in an prolonged-release (XL) formulation (Seroquel XL™) prescribed by psychiatrists to patients with a clinical diagnosis of

schizophrenia and the manic episodes associated with bipolar disorder in a mental health care trust setting in England. This observational study will enable the systematic collection and reporting of safety data on patients newly initiated on treatment with quetiapine XL. Its purpose will be to provide information on a large number of such patients and the treatment they received in a mental health care trust clinical practice setting. Data on patients with a clinical diagnosis of schizophrenia and the manic episodes associated with bipolar disorder newly initiated on treatment with quetiapine IR will also be collected for comparison. Patients will be identified by psychiatrists in England. At start of treatment psychiatrists will recruit appropriate patients into the study and collect baseline details of indication, drug exposure, co-morbidities and other factors. Twelve weeks later, the prescribing psychiatrist will be sent a data-collection end of observation questionnaire about quetiapine treatment. The data collected will be used to examine and compare the safety and prescribing patterns of quetiapine XL and IR, used in the mental health trust setting in England.


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

Networks

Primary Care Research 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

Actual: 16/10/2009

Study start date

Actual: 25/02/2010

Date of final study report

Actual: 18/09/2013

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Astra Zeneca

Regulatory

Was the study required by a regulatory body?

Yes

Is the study required by a Risk Management Plan (RMP)?

EU RMP category 1 (imposed as condition of marketing authorisation)

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
Drug utilisation

Data collection methods:

Primary data collection

Main study objective:

The study was requested by the MHRA for further clarification of safety at higher doses in the Seroquel XL (extended release) formulation in the Mental Health Trust setting. The regulatory commitment is to conduct a study to monitor events in the >600mg XL group and compare them to <600mg XL, with seroquel IR (immediate release preparation) as a comparator.</600mg></600mg>

Study Design

Non-interventional study design

Case-control

Study drug and medical condition

Medicinal product name, other

Seroquel XL

Medical condition to be studied

Schizophrenia

Mania

Population studied

Short description of the study population

Patients with a clinical diagnosis of schizophrenia and the manic episodes associated with bipolar disorder in a mental health care trust 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)
-

Special population of interest

Other

Special population of interest, other

Schizophrenia or mania patients

Estimated number of subjects

900

Study design details

Data analysis plan

Drug utilisation characteristics will be described using summary statistics. Incidence Densities (IDs) will be calculated for the whole 12 week period, for all events reported in patients from the time they start high dose quetiapine (defined as receiving a dose > 600mg) until dose is reduced below 600mg, the patient stops treatment, leaves the care of the psychiatrist, or end of study period, whichever is the soonest. This will be repeated for the XL and IR cohort separately. For each four week period during the 12 week observational period IDs will be calculated for all events reported in patients receiving high dose quetiapine XL (excluding indication related events, which will be listed at analysis stage). Similarly, IDs will be calculated for patients receiving low dose XL. A time to event analysis will be performed in order to investigate the relationship between selected event(s) of interest and potential confounding factors for which information has been requested.

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