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

First published: 20/01/2014
Last updated: 31/03/2024

Study | Finalised

Administrative details

PURI
https://redirect.ema.europa.eu/resource/20672

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 institution and networks

Institutions

Drug Safety Research Unit (DSRU)

United Kingdom
First published: 10/11/2021
Last updated 16/02/2024

Institution | ENCePP partner | Not-for-profit

Networks

Primary Care Research Network

Contact details

Study institution contact
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Study contact

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Primary lead investigator
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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 (extendedrelease) formulation in the Mental Health Trust setting. The regulatory commitment is to conduct a study to monitorevents in the >600mg XL group and compare them to <600mg XL, with seroquel IR (immediate release preparation) as acomparator.</600mg></600mg>

Study Design

Non-interventional study design
Case-control

Study drug and medical condition

Name of medicine, 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, which ever 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

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