Objective assessment of metabolic monitoring in patients treated with Seroquel® or Seroquel® XR/quetiapine fumarate: use of IMS Disease Analyzer to assess physician behaviour in the UK and Germany

First published: 31/01/2013

Last updated: 02/07/2024

Study Finalised

Administrative details

PURI

https://redirect.ema.europa.eu/resource/20619

EU PAS number

EUPAS3292

Study ID

20619

DARWIN EU® study

No

Study countries

- [ ] Germany
- [ ] United Kingdom

Study description

This is a study which will assess the effectiveness of an update to education materials in scope of the EU Risk Management Plan and Summary of Product Characteristics for SEROQUEL® (quetiapine fumarate) Tablets and SEROQUEL XR® (quetiapine fumarate) Extended Release Tablets with respect to evaluation and monitoring for hyperglycaemia and other metabolic parameters for patients treated with quetiapine fumarate. One component to the assessment of effectiveness of risk minimization activity proposed in this study involves evaluation of outcome indicators (evaluation and monitoring of metabolic parameters) by healthcare providers prescribing quetiapine fumarate. To evaluate the effectiveness of the risk minimization activity this study will use an Electronic Medical Records (EMR) approach as a potential means to assess the monitoring of patients and a separate study will evaluate the effectiveness of the metabolic education through use of an objective, easy to understand and complete healthcare provider survey.The evaluation of EMR will determine whether physicians in the UK and Germany perform monitoring of patients treated with quetiapine fumarate (using specific lab tests, measurements and counseling) during encounters with patients and document the proportion of physician encounters within the study sample where patient monitoring is performed.

Study status

Finalised

Research institutions and networks

Institutions

AstraZeneca

First published: 01/02/2024

Last updated: 01/02/2024

Institution

Contact details

Study institution contact

Robert Brody

Study contact

bob.brody@astrazeneca.com

Primary lead investigator

Robert Brody

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 28/01/2013

Actual: 28/01/2013

Study start date

Planned: 01/03/2013

Actual: 01/03/2013

Date of final study report
Planned: 20/12/2013

Actual: 10/12/2013

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

AstraZeneca

Study protocol

D1443C00128 Seroquel Risk Minimization Retrosp Observ DB Study Protocol.pdf
(1.52 MB)

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:

Effectiveness study (incl. comparative)

Data collection methods:

Secondary use of data

Main study objective:

Determine whether physicians in the UK and Germany performmonitoring of patients treated with quetiapine fumurate and quetiapine fumarate XL/XR using select lab tests, measurements and counseling during encounters with patients and to document the proportion of physician encounters within the study sample where patient monitoring is performed.

Study Design

Non-interventional study design

Cross-sectional

Study drug and medical condition

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

QUETIAPINE FUMARATE

Population studied

Short description of the study population

Patients aged 18 and over with diagnoses of schizophrenia, bipolar disorder or major depressive disorder treated with Seroquel® or Seroquel® XR/quetiapine fumarate during the calendar periods 13 February - 31 August 2012 seen by general practitioners or psychiatrists in Germany and patients seen by general practitioners in the UK during the period 11 January 2012 - 31July 2012.

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, bipolar disorder or major depressive disorder patients

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Estimated number of subjects

600

Study design details

Outcomes

The proportion of physician encounters where the following patient monitoring is performed: counseling patients on healthy lifestyle improvements, recording patient weight at initiation of treatment & during on-going treatment, and

monitoring of: hyperlipidemia, signs and symptoms of hyperglycemia, and worsening of glucose control in patients with or at risk for diabetes mellitus

Data analysis plan

Age and risk factor adjusted proportion of patients receiving each metabolic monitoring test/assessment in each country UK and Germany is derived including confidence intervals (95%) associated with the proportions observed. In evaluating patient encounters meeting certainmonitoring characteristics, physician or physician practice is considered.A determination is made as to whether adjustment for any of the following factors is required (for factors with relatively complete ascertainment, > 60%): use of other antipsychotics in addition to quetiapine fumurate in past 6 months, overweight (from physician record based upon BMI > 25), age (50+), female gender, relevant family history, high blood pressure, high cholesterol, and history of cardiovascular disease (in past 12 months), previous lipid panel or blood glucose testing (in the past 12 months).

Documents

Study results

D1443C00128 Clinical Study Report.pdf(1.16 MB)

Study publications

Brody R.S., Liss C.L., Wray H., Iovin R., Michaylira C., Muthutantri, A., Damst...

Data management

Data sources

Data source(s), other

IQVIA Disease Analyzer Germany

Data sources (types)

Other

Data sources (types), other

IMS' LifeLink Disease Analyzer (EMR data) comprises longitudinal patient-level databases from physician practice data systems of office-based physicians in France, Germany, and the United Kingdom (UK). For this study, we will focus on Disease Analyzer data from Germany and the UK.

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