Assessment of physician behaviour regarding metabolic monitoring of patients treated with SEROQUEL® (quetiapine fumarate) Tablets and SEROQUEL® (quetiapine fumarate) Extended Release Tablets in selected countries in the European Union (EU)

First published: 01/02/2013

Last updated: 02/04/2024

Study Finalised

Administrative details

PURI

https://redirect.ema.europa.eu/resource/20622

EU PAS number

EUPAS3287

Study ID

20622

DARWIN EU® study

No

Study countries

- ☐ Germany
- ☐ Hungary
- ☐ Italy
- ☐ Romania
- ☐ Spain
- ☐ Sweden
- ☐ United Kingdom

Study description

This is a study which will assess the effectiveness of an update to health care provider 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. There are 2 components to the assessment of effectiveness proposed in this study: process indicators (receipt and understanding of materials) and outcome indicators (healthcare provider behaviour and effect on patients). To realize these 2 indicators for the evaluation of the effectiveness of the metabolic education: an objective, easy to understand and complete healthcare provider survey is described by this study and the use of an Electronic Medical Records approach, as a potential means to assess the monitoring of patients is described in a separate study.This study involves the evaluation of the effectiveness of the distribution of metabolic educational materials sent to healthcare providers in the EU. It will be conducted via an evaluation survey that uses a questionnaire to assess the receipt of the educational material, whether the material was read, and to

assess healthcare provider behaviour regarding theconduct of monitoring of metabolic parameters for patients treated with SEROQUEL and SEROQUEL XR. The survey will be conducted among healthcare providers who were targeted to receive the educational materials following local guidance and directives.

Study status

Finalised

Research institutions and networks

Institutions

AstraZeneca

First published: 01/02/2024

Last updated: 01/02/2024

Institution

Contact details

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Primary lead investigator

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Study timelines

Date when funding contract was signed
Planned: 31/01/2013

Actual: 31/01/2013

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

D1443C00127 Risk Minimization Physician Survey Protocol1.pdf(1.17 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:

Primary data collection

Main study objective:

The main objective of this study is evaluation of the effectiveness of the distribution of metabolic educational materials sent to healthcare providers in the EU.

Study Design

Non-interventional study design

Cross-sectional

Other

Non-interventional study design, other

Survey of healthcare providers

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

Health Care Professionals who were targeted to receive the metabolic educational materials and either currently prescribe or have the potential to prescribe SEROQUEL or SEROQUEL XR.

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

800

Study design details

Outcomes

An objective assessment is based upon survey responses related to healthcare provider behavior regarding the monitoring of patients (measures of outcome) and having received and read the educational materials (measures of process).

Data analysis plan

Information obtained from responses to each question of the survey will be reported as descriptive statistics. The survey questionnaire contains questions about the specialty of the physician sample completing the survey, questions specific to whether referrals are made to other healthcare providers for metabolic monitoring, whether the healthcare provider conducts monitoring of patients, general questions regarding receipt of the educational materials, and behavior aboutreading the materials. Each risk minimization behavior included in this study (monitoring of weight, hyperglycaemia, lipids, metabolic risk) will be evaluated individually. The following will be reported, as appropriate, as part of this analysis:- Percent of respondents selecting desired response to each question relating to each risk minimization activity and 95% confidence interval- Percent of respondents demonstrating success of composite risk minimization activities and 95% confidence interval.

Documents

Study results

D1443C00127 Clinical Study Report.pdf(404.57 KB)

Study publications

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

Data management

Data sources

Data sources (types)

Other

Data sources (types), other

A healthcare provider survey will document the receipt of educational materials and assess the behaviour of healthcare providers around the key metabolic monitoring messages communicated through the educational materials.

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