WEUKBRE5744: European Survey of Patient and Prescriber Understanding of Risks Associated with TROBALT™ (116771)

First published: 14/06/2013

Last updated: 24/05/2024

Study Finalised

Administrative details

PURI

https://redirect.ema.europa.eu/resource/42075

EU PAS number

EUPAS4126

Study ID

42075

DARWIN EU® study

No

Study countries

☐ Denmark

- [ ] Germany
- [ ] Norway
- [ ] Slovakia
- [ ] Spain
- [ ] Sweden
- [ ] Switzerland
- [ ] United Kingdom

Study description

This is a cross-sectional survey of prescribers and patients on the effectiveness of the physician guide and the patient information leaflet on physician and patient understanding of the significant risks of TROBALT (retigabine). This forms part of the European Risk Management Plan (RMP) requirements.

Study status

Finalised

Research institutions and networks

Institutions

United BioSource Corporation (UBC)

- [ ] Switzerland

First published: 25/04/2013

Last updated: 06/03/2024

Institution | Non-Pharmaceutical company | ENCePP partner

Contact details

Study institution contact

GSK Clinical Disclosure Advisior GSK Clinical Disclosure Advisior

Study contact

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Primary lead investigator

Lianna Ishihara

Primary lead investigator

Study timelines

Date when funding contract was signed

Actual: 18/09/2012

Study start date

Actual: 18/09/2012

Date of final study report

Planned: 27/09/2014

Actual: 31/01/2014

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

GlaxoSmithKline

Study protocol

Redacted 1166771_Protocol_Trobalt_EU_Survey_Amendment 11-Sep-2012_FINAL.pdf(518.37 KB)

WEUKBRE5744-protocol-redact.pdf(622.6 KB)

Regulatory

Was the study required by a regulatory body?

No

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

EU RMP category 3 (required)

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

Data collection methods:

Primary data collection

Main study objective:

The objectives of this study are to assess patients’ and prescribers’ understanding and knowledge of the significant risks associated with TROBALT use as evaluated by a survey instrument.

Study Design

Non-interventional study design

Cross-sectional

Study drug and medical condition

Name of medicine

TROBALT

Medical condition to be studied

Epilepsy

Population studied

Short description of the study population

Neurologists prescribing AEDs and who have been sent the TROBALT Physician's guide.

Inclusion criteria:

1. Must have prescribed an AED at least once in the last 3 months
2. Must be on the list to which the Physician's Guide for TROBALT was distributed

Exclusion:

1. Currently an employee of GSK or UBC

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

350

Study design details

Outcomes

The primary outcome of the survey is the proprtion of patients/neurologists providing correct responses to a series of questions concerning the significant risks associated with TROBALT. The risks evaluated will be those described in the TROBALT PIL and in the Physician's Guide.

Data analysis plan

The population for analysis will comprise all neurologists recruited into the study, meeting eligibility criteria as assessed in the survey screener, and completing the survey.The outcomes (proportion of respondents answering each question correctly) will be summarised for all countries combined, and then for all countries combined not including Germany, with a separate analysis for Germany. The sub-population for analyses will be the neurologists who have ever prescribed TROBALT.For patients, the population for analysis will be all patients included in the study who completed the survey. Patient demographics and indication for TROBALT use will be summarized. The primary outcome is the proportion of patients answering each question correctly. The countries will be combined, with and without Germany. The sub-population for analyses will be by demographic characteristics such as country.

Documents

Study results

116771-clinical-study-report-redact.pdf(627.41 KB)

Data management

Data sources

Data source(s)

Drug claims information system

Data sources (types)

Other

Data sources (types), other

Physician's Survey

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

No