Survey of prescriber understanding of specific risks associated with TROBALT (201426)

First published: 02/04/2014

Last updated: 28/05/2024

Study Finalised

Administrative details

EU PAS number

EUPAS6186

Study ID

42090

DARWIN EU® study

No

Study countries

- Austria
- Belgium
- Bulgaria
- France

Hong Kong
Italy
Norway
Poland
Slovenia
Spain
Switzerland
United Kingdom

Study status

Finalised

Research institutions and networks

Institutions

GlaxoSmithKline (GSK)

First published: 01/02/2024

Last updated: 01/02/2024

Institution

Contact details

Study institution contact

GSK Clinical Disclosure Advisor GSK Clinical Disclosure Advisor Pharma.CDR@gsk.com

Study contact

Pharma.CDR@gsk.com

Primary lead investigator

GSK Clinical Disclosure Advisor GSK Clinical Disclosure Advisor

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 14/02/2014

Actual: 14/02/2014

Study start date

Planned: 14/02/2014

Actual: 14/02/2014

Date of final study report

Planned: 06/04/2015

Actual: 26/08/2015

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

GlaxoSmithKline

Study protocol

prj2250-protocol-redact.pdf (736.84 KB)

201426-protocol-amend-redact.pdf (765.63 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

Study type:

Non-interventional study

Scope of the study:

Other

If ‘other’, further details on the scope of the study

Physician survey

Data collection methods:

Primary data collection

Main study objective:

The objective of this study is to assess prescribers’ awareness of recent label changes, including the appropriate patient population related to retigabine as evaluated by a survey instrument.

Study Design

Non-interventional study design

Cross-sectional

Other

Non-interventional study design, other

Physician survey

Study drug and medical condition

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

RETIGABINE

Population studied

Short description of the study population

Physicians prescribing AEDs and who have been sent a DHCP letter in Austria, Belgium, France, Hongkong,Italy, Norway, Poland, Slovakia, Spain, Switzerland and the United Kingdom.

Physicians will be required to meet all the following inclusion criteria:
1. Must manage patients with epilepsy.
2. Must have prescribed an AED at least once in the last 6 months.
3. Must be on the list to which a DHCP letter was distributed in June 2013.

Physicians meeting any of the following criteria will not be eligible to take the survey:
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

0

Study design details

Outcomes

The proportion of physicians providing correct responses to a series of questions concerning specific risks associated with retigabine

---

Data analysis plan

The outcome of the survey is the proportion of physicians providing correct responses to a series of questions concerning specific risks associated with retigabine. Additional analyses will compare the level of understanding between physicians who have prescribed retigabine and those who have never or not recently prescribed the product.

Documents

Study results

gsk-201426-clinical-study-report-redact.pdf (1.59 MB)

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

Physician 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