REVIEU - A multinational, retrospective, observational drug utilisation study of REVOLADE™ (eltrombopag) In selected countries in the European Union (201108)

First published: 30/06/2014

Last updated: 02/07/2024

Study Finalised

Administrative details

EU PAS number

EUPAS6969

Study ID

16500

DARWIN EU® study

No

Study countries

France

Germany

Greece

Italy

Spain

Study description

Chronic primary immune thrombocytopenia (ITP) is an acquired immune mediated disorder characterized by isolated thrombocytopenia, defined as a peripheral blood platelet count less than 100 x 10ˆ9/L, lasting for more than 12 months, and the absence of any underlying cause. In patients with chronic Hepatitis C virus (HCV), thrombocytopenia occurs most commonly in those with progressive liver disease and cirrhosis. In such patients, thrombocytopenia may render patients ineligible for antiviral treatment and require dose reductions or discontinuation and may also prevent patients from having liver biopsies and other invasive procedures, thereby hampering a physician’s ability to stage and monitor the patient’s liver condition. REVOLADE (eltrombopag, GlaxoSmithKline, Research Triangle Park, NC, USA) is an oral, non-peptide, thrombopoietin receptor (TPO-R) agonist that interacts with the TPO-R and induces differentiation of hematopoietic stem and progenitor cells to megakaryocytes, and has been approved for the treatment of adults with chronic ITP and chronic HCV associated thrombocytopenia. It is generally acknowledged that prescribing practices of any particular drug in real life clinical practice may differ from its use as defined in the authorized indications. This drug utilisation study (DUS) for REVOLADE will be conducted in several European countries to determine the indications for use and patient age ranges for which REVOLADE is currently being prescribed. This is a multi-national, multi-center study involving the retrospective review of approximately 300 to 450 patient medical records from selected European countries including France, Germany, Spain, Italy and Greece.

Study status

Finalised

Research institutions and networks

Institutions

Scientific Affairs, Outcome SARL

Switzerland

First published: 12/04/2010

Last updated: 20/08/2024

Institution | Other

Contact details

Study institution contact

GSK Clinical Disclosure Advisor GSK Clinical Disclosure Advisor trialandresults.registries@novartis.com

Study contact

trialandresults.registries@novartis.com

Primary lead investigator

GSK Clinical Disclosure Advisor GSK Clinical Disclosure Advisor

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 28/08/2013

Actual: 28/08/2013

Study start date
Planned: 01/09/2014

Actual: 27/05/2014

Date of final study report
Planned: 19/06/2016

Actual: 19/06/2016

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

GlaxoSmithKline

Study protocol

weukbre7133-protocol-redact.pdf (1.49 MB)

gsk-201108-protocol-redact.pdf (1.86 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 topic:

Human medicinal product

Study type:

Non-interventional study

Scope of the study:

Drug utilisation

Data collection methods:

Secondary use of data

Main study objective:

To determine indications for use among REVOLADE users within several EU countries utilizing real-world data obtained in medical records, to document REVOLADE utilisation patterns, classified according to the medical conditions and the patient age categories for which REVOLADE is being prescribed in selected European countries, and to characterize the patients who are prescribed REVOLADE.

Study Design

Non-interventional study design

Other

Non-interventional study design, other

Retrospective review of medical records

Study drug and medical condition

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

ELTROMBOPAG

Population studied

Short description of the study population

Patients being treated with REVOLADE at approximately 18-21 hospital/ward or office based sites in selected European countries including France, Germany, Spain, Italy and Greece.

Age groups

- Term newborn infants (0 – 27 days)
- Infants and toddlers (28 days – 23 months)
- Children (2 to < 12 years)
- Adolescents (12 to < 18 years)
- 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

450

Study design details

Outcomes

Patient age, patient gender, diagnosis for which REVOLADE was prescribed, and REVOLADE dose, Treatment(s) preceding REVOLADE prescription, concomitant treatment(s) initiated with REVOLADE, and platelet counts

Data analysis plan

Continuous variables will be reported as mean, standard deviation, median and range. Categorical variables will be summarised as number and proportion of the total study population (counting missing data as a class), and by subgroups, where appropriate. Confidence intervals (as 95% CI) will be calculated using the method outlined by Newcombe, 1998 for the key variables.

Documents

Study results

gsk-201108-clinical-study-report-redact.pdf (9.63 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

Medical records

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