WEUSKOP7136: A global, prospective cohort study to evaluate the real-world use of eltrombopag in adult patients with chronic Hepatitis C Virus infection who are unable to initiate or maintain optimal interferon-based therapy due to thrombocytopenia (201111)

First published: 06/08/2014

Last updated: 30/03/2024

Study Finalised

Administrative details

EU PAS number

EUPAS7201

Study ID

20455

DARWIN EU® study

No

Study countries

Canada

Greece

Italy

Russian Federation

Spain

United States

Study description

Eltrombopag is a 2nd generation oral thrombopoeitin receptor agonist developed by GlaxoSmithKline (GSK) and approved for the treatment of chronic immune (idiopathic) thrombocytopenia (ITP) and hepatitis C associated thrombocytopenia. The aim of this study is to assess the safety and effectiveness of eltrombopag in routine clinical practice in patients with HCV who are unable to initiate or maintain optimal interferon-based therapy due to thrombocytopenia.This study is a global, multi-center, prospective, observational studyconducted to evaluate clinical outcomes and treatment patterns in HCV patients treated with eltrombopag. Patients will be followed for a period of 3 years after initiating eltrombopag, based on routine care, patients will be assessed approximately every 3 months or according to routine practice during interferon-based therapy and then approximately every 6 months thereafter according to local standard practice.

Study status

Finalised

Research institutions and networks

Institutions

Novartis Pharmaceuticals

First published: 01/02/2024

Last updated: 01/02/2024

Institution

Multiple centres: 40 centres are involved in the study

Contact details

Study institution contact

Clinical Disclosure Officer Clinical Disclosure Officer
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Study contact

trialandresults.registries@novartis.com

Primary lead investigator

Clinical Disclosure Officer Clinical Disclosure Officer

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 31/10/2013

Actual: 31/10/2013

Study start date
Planned: 28/11/2014

Actual: 16/07/2014

Date of final study report
Planned: 30/11/2019

Actual: 09/06/2017

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Novartis

Study protocol

Epi-WEUSKOP7136-protocol-redact.pdf (1.49 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 topic:

Disease /health condition

Human medicinal product

Study type:

Non-interventional study

Scope of the study:

Assessment of risk minimisation measure implementation or effectiveness

Disease epidemiology

Effectiveness study (incl. comparative)

Data collection methods:

Secondary use of data

Main study objective:

The aim of this study is to assess the safety and effectiveness of eltrombopag in routine clinical practice in patients with HCV who are unable to initiate or maintain optimal interferon-based therapy due to thrombocytopenia.

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

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

ELTROMBOPAG

Medical condition to be studied

Hepatitis C

Thrombocytopenia

Population studied

Short description of the study population

Patients aged ≥ 18 years with Hepatitis C Virus (HCV) who were unable to initiate or maintain optimal interferon-based therapy due to thrombocytopenia. Patients with diagnosis of HCV verified by the presence of detectable HCV RNA, initiation of first-time treatment with eltrombopag no more than 3 months prior to study enrolment, unable to initiate, maintain, or restart optimal interferon-based therapy due to thrombocytopenia prior to initiating eltrombopag, currently undergoing interferon-based antiviral therapy planned, willing and able to provide written informed consent were included.

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

Hepatic impaired

Estimated number of subjects

200

Study design details

Outcomes

The primary objective of the study is to assess and compare the incidence of hepatic decompensation and mortality at 3 years in patients who achieve sustained viral response (SVR) with patients who do not achieve SVR. To assess the incidence of thromboembolic events among new users of eltrombopag and treatment effectiveness with respect to initiating, maintaining and completing antiviral therapy and achieving SVR. All-cause and cause-specific mortality risk will be evaluated and factors related to the risk of hepatic decompensation and thromboembolic events will be explored in users.

Data analysis plan

Descriptive analyses will include tables and figures showing patient demographics and characteristics of study patients including medical/disease history, virology, and laboratory information, at baseline and at 6 months, 12 months, 18 months, 24 months and 36 months of follow-up. Information will be presented for all patients and stratified by subgroups of interest, to the extent allowed by the data.Kaplan-Meier survival estimates will be calculated for 6, 12, 18, 24, and 36 month observation periods for the outcomes of hepatic decompensation, thromboembolic events and all-cause mortality. Cumulative incidence rates will be calculated for the occurrence of hepatic decompensation and thromboembolic events, as separate events, over the same observation periods. For hepatic decompensation or mortality at 3 years (as separate events), incidence rate ratios comparing patients who did and did not attain SVR will be calculated, along with 95% confidence intervals (CIs).

Documents

Study results

ETB115A2409_EUPAS7201.pdf (5.52 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

Prospective patient-based data collection

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