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

PURI
https://redirect.ema.europa.eu/resource/20455

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 institution 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
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 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
Disease epidemiology
Effectiveness study (incl. comparative)

Data collection methods:
Secondary data collection

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

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