WEUSKOP7135: A prospective, observational cohort study nested within the HCV TARGET study to evaluate real-world use (201110)

First published: 22/08/2014

Last updated: 30/03/2024

Study Finalised

Administrative details

PURI

https://redirect.ema.europa.eu/resource/18675

EU PAS number

EUPAS7309

Study ID

18675

DARWIN EU® study

No

Study countries

- [ ] Canada
- [ ] France
- [ ] Germany
- [ ] Israel
- [ ] Puerto Rico
- [ ] Spain
- [ ] United Kingdom
- [ ] 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 report the incidence of hepatic decompensation among eltrombopag user with chronic hepatitis C virus infection who are unable to initiate or maintain optimal interferon-based therapy due to thrombocytopenia.This study is a multi-center, prospective, observational studynested within the HCV TARGET study, and conducted to evaluate patients treated with eltrombopag. Patients will be followed for a period of up to 3 years after initiating eltrombopag, based on routine care, patients will be assessed regularly during interferon-based therapy and thereafter according to local standard practice

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Study status

Finalised

Research institutions and networks

Institutions

Novartis Pharmaceuticals

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Institution

Multiple centres: 100 centers 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: 31/10/2014

Actual: 12/08/2014

Date of final study report
Planned: 31/07/2018

Actual: 25/08/2016

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Novartis

Study protocol

Epi-Prot-WEUSKOP7135-protocol-redact.pdf(679.16 KB)

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 report the incidence of hepatic decompensation among eltrombopag users with chronic hepatitis C virus infection 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

Population studied

Short description of the study population

Patients with chronic hepatitis C virus infection who receive eltrombopag therapy with interferon-based therapy that also includes direct acting anti-viral agents.

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

58

Study design details

Outcomes

The aim of this study is to report the incidence of hepatic decompensation among eltrombopag users with chronic hepatitis C virus infection who are unable to initiate or maintain optimal interferon-based therapy due to thrombocytopenia. Secondary objectives include reporting incidence of thromboembolic events and mortality and identifying risk factors for hepatic decompensation, thromboembolic events and mortality among eltrombopag users in a real-world setting. The study will also report the 3- year incidence of hepatic decompensation and mortality, and examine effectiveness of eltrombopag to initiate and maintain HCV therapy.

Data analysis plan

Cumulative incidence rates and corresponding 95% confidence intervals as well as Kaplan-Meier rates and corresponding 95% confidence intervals will be calculated for the occurrence of hepatic decompensation, thromboembolic events, or mortality, as separate events, at multiple time points during and at the end of the 3-year followup period. Baseline factors potentially predictive of events will be identified through Kaplan-Meier survival estimates for patients with vs. without the factor and testing for statistical significance using the log-rank test. Cox proportional hazards models will be constructed to evaluate the influence of these identified factors simultaneously.

Documents

Study results

ETB115A2408-CSR_Redacted.pdf(3.27 MB)

Data management

Data sources

Data sources (types)

Disease registry

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