Drug Utilization of Boceprevir and Clinical Management of Health Outcomes of Interest in Chronic Hepatitis C Patients (P08518)

First published: 13/07/2012

Last updated: 02/07/2024

Study Finalised

Administrative details

PURI

https://redirect.ema.europa.eu/resource/24508

EU PAS number

EUPAS2768

Study ID

24508

DARWIN EU® study

No

Study countries

- [ ] France
- [ ] Germany
- [ ] Spain
- [ ] United Kingdom

Study description

This will be an observational study of the routine clinical management of patients infected with Chronic Hepatitis C (CHC) genotype-1. Primary data collection on physicians treating CHC and patients infected with CHC will be performed in approximately 4 European countries (the exact number and final selection of countries will depend on market uptake of Victrelis™(Boceprevir). This study is not intended to change the patient/physician relationship, nor influence the physician’s drug prescription or therapeutic management of the patient. Physicians that treat CHC will provide aggregated site level information about current patterns of CHC treatment via a drug utilization questionnaire. Baseline patient information and data on the occurrence, clinical management of protocol-defined HOIs (anemia, neutropenia, thrombocytopenia, rash) will be collected via eCRF among patients initiating Victrelis in combination with P-R, Incivo in combination with P-R or P-R only regimens. Data will be collected every 8 weeks for up to 48 weeks of treatment.

Study status

Finalised

Research institutions and networks

Institutions

ICON Commercialisation & Outcomes

☐ Germany

☐ Ireland

First published: 19/03/2010

Last updated: 05/07/2024

Institution | Non-Pharmaceutical company | ENCePP partner

Multiple centres: 80 centres are involved in the study

Contact details

Study institution contact

Christopher Mast

Study contact

christopher_mast@merck.com

Primary lead investigator

Christopher Mast

Primary lead investigator

Study timelines

Date when funding contract was signed
Planned: 09/09/2011

Actual: 20/05/2011

Study start date
Planned: 29/05/2012

Actual: 21/05/2012

Data analysis start date
Planned: 30/06/2015

Actual: 06/07/2015

Date of interim report, if expected
Planned: 16/12/2014

Date of final study report
Planned: 30/04/2016

Actual: 10/05/2016

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Merck, Sharp & Dohme

Study protocol

Final Redactions Applied_ P08518 Victrelis PASS Protocol.pdf(2.38 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:

Drug utilisation

Other

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

This is a drug utilisation study, however, we will also assess the occurence and management of pre-specified protocol defined HOIs (i.e. anemia, neutropenia, thrombocytopenia, and rash) in a real world clinical setting.

Data collection methods:

Primary data collection

Main study objective:

Describe drug utilization patterns, baseline patient and disease characteristics, and clinical management of pre-specified protocol-defined health outcomes of interest (HOI): anemia, neutropenia, thrombocytopenia and rash - among genotype-1 treatment-naive and/or previous treatment failure patients initiating treatment with Victrelis™ with P-R, Incivo™ with P-R, or P-R alone (without other DAA).

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

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

BOCEPREVIR

TELAPREVIR

RIBAVIRIN

PEGINTERFERON ALFA-2A

PEGINTERFERON ALFA-2B

Medical condition to be studied

Hepatitis C

Anaemia

Thrombocytopenia

Neutropenia

Rash

Population studied

Short description of the study population

Physicians and patients infected with chronic Hepatitis C genotype-1 from atleast 4 European countries.

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

1000

Study design details

Outcomes

1st Primary: Proportion of CHC patients initiating Victrelis™ with P-R relative to Incivo™ with P-R or P-R only. 2nd primary: Proportion of CHC patients initiating any of the treatment above by patient and disease characteristics. 3rd primary: Description of the occurrence & clinical management of HOI's in the treatment

groups specified above. The secondary outcomes of interest are the incidence rates (per unit person time) for protocol defined anemia, neutropenia, thrombocytopenia and rash for the CHC treatment groups in the study.

Data analysis plan

All data will be analyzed in a descriptive manner, no formal hypotheses will be tested. Frequencies and incidence rates of Health outcomes of interest (HOIs) will be summarized. Clinical characteristics of the study population will be analyzed by frequency and percentages for categorical variables and by mean, standard deviation, minimum, median, and maximum for continuous variables.

Documents

Study results

Final Redactions Applied_P08518 Victrelis PASS Report Abstract_Redacted.pdf (560.3 KB)

P08518 Victrelis PASS Final Report Summary 20170427.pdf(1.23 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