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





Administrative details

EU PAS number
EUPAS2768
Study ID
24508
DARWIN EU® study
No
Study countries
France
Germany
Spain

United	Kingdom
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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

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Institution

Non-Pharmaceutical company

ENCePP partner

Multiple centres: 80 centres are involved in the

study

Contact details

Study institution contact

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Study contact

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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?

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 occurrence and management of pre-specified protocol defined HOIs (i.e. anemia, neutropenia, thrombocytopenia, and rash) in a real world clinical setting.

Data collection methods:

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

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

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 Mode	el (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