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 institution and networks

Institutions

ICON Commersialisation & Outcomes (MAPI-ICON), ICON

Germany
First published: 19/03/2010
Last updated
06/03/2024

Institution

ENCePP partner

Non-Pharmaceutical company

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?
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