Multicenter, Non-Interventional, Retrospective, Matched Cohort Study of Patients Monoinfected with Chronic Hepatitis B and with Moderate or Severe Renal Impairment Treated with Viread® or Baraclude® (ReCoRd)

First published: 23/03/2016

Last updated: 01/04/2024

Study Finalised

Administrative details

PURI

https://redirect.ema.europa.eu/resource/25333

EU PAS number

EUPAS12897

Study ID

25333

DARWIN EU® study

No

Study countries

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

Study description

GS-EU-174-1846: The primary objective of this study was to retrospectively evaluate the safety of Viread® among adult chronic hepatitis B patients with moderate or severe renal impairment, focusing on renal events of special interest.

Study status

Finalised

Research institutions and networks

Institutions

Gilead Sciences

First published: 12/02/2024

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Institution | Pharmaceutical company

Multiple centres: 55 centres are involved in the study

Contact details

Study institution contact

Gilead Study Director

Study contact

ClinicalTrialDisclosure@gilead.com

Primary lead investigator

Gilead Study Director

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 23/11/2015

Actual: 23/11/2015

Study start date

Planned: 30/06/2016

Actual: 30/06/2016

Data analysis start date

Planned: 02/10/2017

Actual: 23/11/2017

Date of final study report

Planned: 30/03/2018

Actual: 05/03/2018

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Gilead Sciences Europe Ltd.

Study protocol

protocol+GS-EU-174-1846_v1.2_approved signed.pdf(1.63 MB)

amd-1-prot GS-EU-174-1846.pdf(761.58 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 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

Effectiveness study (incl. comparative)

Data collection methods:

Secondary use of data

Main study objective:

To retrospectively evaluate the safety of Viread® among chronic hepatitis B patients with moderate or severe renal impairment, focusing on renal events of special interest.

Study Design

Non-interventional study design

Other

Non-interventional study design, other

Retrospective matched cohort study

Study drug and medical condition

Medical condition to be studied

Hepatitis B

Renal impairment

Population studied

Short description of the study population

Adult chronic hepatitis B patients who had been treated with Viread® (monotherapy), administered either as oral granules once daily and/or as a tablet formulation once daily or in prolonged dosing intervals or patients who had been treated with Baraclude® (monotherapy) as a tablet formulation once daily and/or as oral solution at any time between 23rd April 2008 (Centralized European marketing authorization approval date for Viread® tablets in HBV indication) and 31st December 2015. Also included patients who had experienced at least one occurrence of moderate or severe renal impairment with CrCL between 20-60 mL/min inclusive (based on Cockcroft-Gault formula), while treated with Viread® or Baraclude®.

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

Renal impaired

Estimated number of subjects

1000

Study design details

Outcomes

Renal events of special interest were defined as:- Presence of proximal tubulopathy (PRT)- Renal AEs leading to withdrawal of either Viread® or Baraclude® treatment- Renal AEs leading to dialysis- Renal SAEs including deaths- Decline in renal function if reported as an AE, To describe the effectiveness of Viread® in the treatment of chronic hepatitis B in patients with moderate or severe renal impairment.To compare safety and effectiveness between Viread® and Baraclude® among the matched study cohort arms.

Data analysis plan

Data was summarized using univariate descriptive statistics. Continuous variables were summarized by mean, standard deviation, median, lower quartile, upper quartile, minimum and maximum. Categorical variables were summarized by number and percentage of patients in each categorical definition including according 95% confidence intervals.Multivariate analyses were used to estimate adjusted rates and proportions. In order to maximize homogeneity between the two cohorts and reduce the impact of treatment-selection bias a retrospective propensity score matching (PSM) approach was applied to enable usage of Inverse Probability Treatment Weighting analysis techniques. Conditional multivariate logistic regression models were used to assess differences between the two study cohorts.

Documents

Study results

GS-EU-174-1846 CSR Abstract_f-redact.pdf(323.27 KB)

Study publications

Poster THU-053 presented at EASL 2018: Moderate and Severe Renal Impairment in ...

Data management

Data sources

Data sources (types)

Other

Data sources (types), other

Retrospective patient-based data collection. The primary data source were the patients' medical records.

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