A Multinational Observational Registry Collecting Data on the Profile of Patients with Chronic Hepatitis D Virus Infection Receiving Treatment with Bulevirtide (MYR-Reg-02)

First published: 23/12/2020

Last updated: 07/06/2024

Study Finalised

Administrative details

EU PAS number

EUPAS38678

Study ID

44022

DARWIN EU® study

No

Study countries

- ☐ Austria
- ☐ France

Germany

Study description

MYR-Reg-02: The primary objective of this study was to collect data on the rate of liver-related clinical events in participants with chronic hepatitis D virus (HDV) infection and compensated liver disease receiving buleviride (BLV) treatment. The study was terminated prematurely following Gilead's decision to replace the study with a global registry Study GS-US-589-6206.

Study status

Finalised

Research institutions and networks

Institutions

Gilead Sciences

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Institution | Pharmaceutical company

Contact details

Study institution contact

Gilead Study Director ClinicalTrialDisclosure@gilead.com

Study contact

ClinicalTrialDisclosure@gilead.com

Primary lead investigator

Gilead Study Director

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 04/12/2020

Actual: 15/12/2020

Study start date

Planned: 01/03/2021

Actual: 04/12/2020

Date of final study report

Planned: 31/12/2022

Actual: 01/05/2024

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Gilead Sciences

Study protocol

MYR-Reg-02-appendix-16.1.1-protocol v1.2_f-redact.pdf(1.05 MB)

Regulatory

Was the study required by a regulatory body?

No

Is the study required by a Risk Management Plan (RMP)?

Not applicable

Methodological aspects

Study type

Study type list

Study type:

Non-interventional study

Scope of the study:

Disease epidemiology

Effectiveness study (incl. comparative)

Main study objective:

Rate of liver-related clinical events in participants receiving BLV treatment: cirrhosis development, hepatic decompensation, jaundice, hepatocellular carcinoma (HCC) development, liver transplantation, and liver-related death.

Study Design

Non-interventional study design

Cohort

Other

Non-interventional study design, other

Non-interventional observational study, no test for formal hypothesis

Study drug and medical condition

Name of medicine

HEPCLUDEX

Anatomical Therapeutic Chemical (ATC) code

(J05AX28) bulevirtide

bulevirtide

Medical condition to be studied

Hepatitis D

Liver disorder

Additional medical condition(s)

Adult participants who have been diagnosed with chronic HDV infection by HDV RNA,positive plasma (or serum) and compensated liver disease, confirmed by respective,documentation in the participant’s medical records.

Population studied

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)

Estimated number of subjects

100

Study design details

Data analysis plan

Continuous variables were summarized in terms of descriptive statistics including number of observations, mean, standard deviation, minimum, maximum and quartiles. Categorical variables were summarized in terms of frequencies and percentages. To account for the different durations of observation, the incidences of events were normalised to participant exposure to evaluate the incidence according to time of exposure (patient-years). An appropriate time window pattern relative to baseline (enrolment) was defined for the Registry data (e.g. months or quarters). Longitudinal data were summarized by time window. When more than one measurement for a participant falls into the same time window the last measurement was used. Summaries were provided by country and relevant concomitant treatment cohort.

Documents

Study report

CSR-Final-Synoptic-MYR-REG-02_f-redact.pdf(840.96 KB)

Data management

Data sources (types)

Electronic healthcare records (EHR)

Use of a Common Data Model (CDM)

CDM mapping

No

Data quality specifications

Check conformance

Yes

Check completeness

Yes

Check stability

Yes

Check logical consistency

Yes

Data characterisation

Data characterisation conducted

Yes