VIR-Life: Prospective assessment of the real-life treatment outcomes of six years of Viread® in CHB following-up on the German Multicenter Non-Interventional Study GEMINIS

First published: 28/06/2013

Last updated: 29/03/2024

Study Finalised

Administrative details

PURI

https://redirect.ema.europa.eu/resource/17262

EU PAS number

EUPAS4215

Study ID

17262

DARWIN EU® study

No

Study countries

Germany

Study description

The real-life treatment outcomes of Viread® have been investigated in GEMINIS for a period of 3 years. VIR-Life is the roll-over non-interventional study from GEMINIS to allow the prospective evaluation of the real-life treatment outcomes for additional 3 years. The primary objective of this study is as follows:Prospectively describe the virological response, defined as HBV-DNA concentration, during 6 years Viread® treatment for CHB in a real life setting. The secondary objectives of this study are to evaluate the: Safety and tolerability of 6 years of Viread® in CHB in a real life setting (Adverse drug reactions (AR) (unrelated Adverse Events (AEs) will also be listed in the report), Renal safety, Estimated creatinine clearance (eCrCl), Serum creatinine level, Serum phosphorus level),and histological improvement of the liver.Duration of Study: 3 years after rolling over from GEMINISStudy Size: 150 patientsLocation: Germany, 23 sites

Study status

Finalised

Research institutions and networks

Institutions

Gilead Sciences

First published: 12/02/2024

Last updated: 12/02/2024

Institution | Pharmaceutical company

Multiple centres: 23 centres are involved in the study

Contact details

Study institution contact

Gilead Study Director

Study contact

GileadClinicalTrials@gilead.com

Primary lead investigator

Gilead Study Director

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 15/05/2013

Actual: 15/05/2013

Study start date

Planned: 17/07/2013

Actual: 29/07/2013

Data analysis start date
Planned: 18/06/2014

Actual: 22/06/2015

Date of interim report, if expected
Planned: 30/09/2014

Actual: 21/09/2015

Date of final study report
Planned: 28/04/2017

Actual: 16/12/2016

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Gilead Sciences GmbH

Study protocol

protocol GS-DE-174-0225 FINAL COMPLETE.pdf(743.85 KB)

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 topic:

Disease /health condition

Human medicinal product

Study type:

Non-interventional study

Scope of the study:

Drug utilisation

Data collection methods:

Secondary use of data

Main study objective:

Describe the virological response, defined as HBV-DNA concentration, during 6 years Viread® treatment for CHB in a real life setting.

Study Design

Non-interventional study design

Cohort

Other

Non-interventional study design, other

Case-series

Study drug and medical condition

Name of medicine

VIREAD

Medical condition to be studied

Chronic hepatitis B

Population studied

Short description of the study population

Adult, Hepatitis B Virus (HBV)-mono-infected Chronic hepatitis B (CHB) patients who started CHB treatment with Viread® in GEMINIS and completing 3 years in GEMINIS and still receiving a Viread®.

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

150

Study design details

Outcomes

HBV-DNA concentration after 6 year TDF, ALT levels throughout 6 years TDFRenal function parameters throughout 6 years TDFLiver synthesis parameters throughout 6 years TDFLiver histology improvements throughout 6 years TDFAdverse Reactions to TDF throughout 6 years TDF

Data analysis plan

Descriptive analysis:Categorical and ordinal variables will be described by sample size and the frequency of each modality (over the total number of responses).Quantitative variables will be described by the number of responses, mean, standard deviation, minimum, maximum, median of all available data.Inferential analysis: When deemed necessary, sub-group comparisons and/or between time point comparisons may be implemented.Patients who are lost to follow-up or discontinue therapy for any reason, including leaving the study for non-medical reasons will be censored at the discontinuation date. Person time will be computed from baseline to discontinuation and used as such for any time to event analysis.Multivariate analysis:The potential dependence of treatment outcome frequency with other variables or baseline characteristics will be investigated through multivariate analysis.

Documents

Study results

VIR_life_synopsis_16Dec2016.pdf(329.34 KB)

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