Viread Observational, Cross -Sectional Drug Utilisation Study in Children and Adolescents with Chronic Hepatitis B (Viread HBV DUS)

First published: 02/07/2014

Last updated: 01/04/2024

Study Finalised

Administrative details

PURI

https://redirect.ema.europa.eu/resource/24963

EU PAS number

EUPAS6987

Study ID

24963

DARWIN EU® study

No

Study countries

- [ ] Austria
- [ ] Belgium
- [ ] Bulgaria
- [ ] Denmark
- [ ] Estonia
- [ ] France
- [ ] Germany
- [ ] Hungary
- [ ] Italy
- [ ] Netherlands
- [ ] Poland
- [ ] Portugal
- [ ] Romania
- [ ] Spain
- [ ] Sweden
- [ ] United Kingdom

Study description

GS-EU-174-0224: This observational cross-sectional drug utilisation study uses a study-specific questionnaire that will capture the respective aggregated data on Viread use, pre-treatment and on-treatment assessments and management of renal and bone toxicities. The participating physicians will complete questionnaires using their patient medical records retrospectively. Data will not be collected on the individual patient level, but will be aggregated at the site level. Physicians will be sent 3 separate questionnaires over a 3-year period on information regarding paediatric patients with CHB under care in their practices.

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: 35 centres are involved in the study

Contact details

Study institution contact

Gilead Study Director

Study contact

ClinicalTrialDisclosures@gilead.com

Primary lead investigator

Gilead Study Director

Primary lead investigator

Study timelines

Date when funding contract was signed
Planned: 28/11/2014

Actual: 24/11/2014

Study start date
Planned: 03/03/2015

Actual: 06/02/2015

Date of interim report, if expected
Planned: 29/05/2015

Actual: 29/06/2015

Date of final study report
Planned: 31/05/2018

Actual: 07/05/2018

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Gilead Sciences Inc.

Study protocol

amd-1-prot GS-EU-174-0224 FINAL COMPLETE.pdf(259.01 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:

Drug utilisation

Data collection methods:

Secondary use of data

Main study objective:

To describe the characteristics of chronic hepatitis B patients less than 18 years old treated within the EU with Viread

Study Design

Non-interventional study design

Cross-sectional

Study drug and medical condition

Medical condition to be studied

Chronic hepatitis B

Population studied

Short description of the study population

All Chronic Hepatitis B (CHB) patients who initiate therapy with Viread before the age of 18 years. The participating physicians will complete questionnaires using their patient medical records retrospectively. Data will not be collected on the individual patient level, but will be aggregated at the site level.

Age groups

Children (2 to < 12 years)

Adolescents (12 to < 18 years)

Special population of interest

Hepatic impaired

Estimated number of subjects

100

Study design details

Outcomes

To describe the characteristics of chronic hepatitis B patients less than 18 years old treated within the EU with Viread, To describe how the pre-treatment and on treatment renal function and bone mineral density are monitoredTo determine if a multidisciplinary approach is taken in paediatric patient management, including renal and bone toxicities.

Data analysis plan

Data from the surveys of prescribers of Viread to adolescents and children with CHB will be summarized descriptively (numbers, ranges, proportions)

Documents

Study results

GS-EU-174-0224 CSR Synopsis_f-redact.pdf(230.04 KB)

Data management

Data sources

Data sources (types)

Electronic healthcare records (EHR)

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