GS-EU-337-1820 - An Observational Drug Utilization Study of Ledipasvir/Sofosbuvir and Tenofovir Disoproxil Fumarate + Pharmacokinetic Enhancer Co-Administration in Adults Co-Infected with Chronic Hepatitis C and HIV-1 Infections (HAVEN co-infection study)

First published: 20/07/2016

Last updated: 16/02/2024

Study Finalised

Administrative details

EU PAS number

EUPAS14114

Study ID

25605

DARWIN EU® study

No

Study countries

- [ ] France
- [ ] Germany
- [ ] Ireland
- [ ] Italy
- [ ] Poland
- [ ] Portugal
- [ ] Spain
- [ ] Sweden
- [ ] United Kingdom

Study description

This non-interventional, prospective drug utilization study will assess the utilization of Harvoni and TDF+PK enhancers among chronic HCV and HIV-1 co-infected patients ≥ 18 years of age that are prescribed Harvoni whilst receiving any HIV treatment regimen in Europe. The objectives of this study are as follows:Primary - To characterize the frequency of co-administration of Harvoni with TDF + PK enhancers in the post-marketing setting.Secondary - To characterize renal adverse events (serious and non-serious) and renal function testing in concomitant users of Harvoni and TDF+PK enhancers.Exploratory - To assess HIV-treatment regimen changes with Harvoni utilization.

Study status

Finalised

Research institutions and networks

Institutions

Gilead Sciences

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Institution | Pharmaceutical company

Multiple centres: 41 centres are involved in the study

Contact details

Study institution contact

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Study contact

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Primary lead investigator

Iain Black

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 05/01/2016

Actual: 05/01/2016

Study start date
Planned: 30/12/2016

Actual: 13/12/2016

Date of interim report, if expected
Actual: 06/07/2017

Date of final study report
Planned: 29/05/2020

Actual: 14/12/2017

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Gilead Sciences Europe Limited

Study protocol

GS-EU-337-1820 Original Protocol 16 March 2016 FINAL.pdf(600.49 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:

Primary data collection

Main study objective:

To characterize the frequency of co-administration of Harvoni with Tenofovir Disoproxil Fumarate + Pharmacokinetic Enhancer in the post-marketing setting.

Study Design

Non-interventional study design

Cohort

Other

Non-interventional study design, other

Drug interaction study

Study drug and medical condition

Anatomical Therapeutic Chemical (ATC) code

(J05AX65) sofosbuvir and ledipasvir

sofosbuvir and ledipasvir

Medical condition to be studied

Hepatitis C

Human immunodeficiency virus transmission

Population studied

Short description of the study population

Hepatitis C virus and HIV-1 co-infected subjects receiving anti-retroviral therapy who initiate treatment with Harvoni.

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

Immunocompromised

Estimated number of subjects

2000

Study design details

Data analysis plan

The proportion of subjects with concomitant Harvoni and TDF+PK enhancer use will be estimated with 95% confidence intervals (CIs) among all HCV-HIV co-infected, Harvoni-treated subjects included in the study. Also, baseline information on subject demographics and other clinical characteristics will be summarized using descriptive statistics (i.e. sample size, mean, standard deviation, median, and interquartile range) for continuous data and by the numbers and percentages of subjects for categorical data. The incidence rate of renal AEs with 95% CIs will be assessed, taking into account the person-time of subjects with concomitant Harvoni and TDF+PK enhancer utilization. In addition, the incidence rates of specific renal AEs that have been previously studied in TDF-treated patients will be estimated. Also, the clinical characteristics and changes in renal-associated laboratory measurements of subjects will be evaluated

Documents

Study results

GS-EU-337-1820 Annual Progress Report.pdf(1.31 MB)

Study report

GS-EU-337-1820 Interim Progress Report.pdf(1.27 MB)

Data management

ENCePP Seal

The use of the ENCePP Seal has been discontinued since February 2025. The ENCePP Seal fields are retained in the display mode for transparency but are no longer maintained.

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

No