Observational, Cross-Sectional Post-Authorisation Safety Study to Assess Healthcare Provider Awareness of Risks Related to Sofosbuvir and Ledipasvir/Sofosbuvir (EU HVN SOF Survey Study)

First published: 08/09/2016

Last updated: 31/03/2024

Study Finalised

Administrative details

EU PAS number

EUPAS15103

Study ID

20772

DARWIN EU® study

No

Study countries

- [ ] Bulgaria
- [ ] Denmark
- [ ] France
- [ ] Germany
- [ ] Hungary
- [ ] Spain
- [ ] United Kingdom

Study description

Investigate healthcare provider awareness of the risk of clinically significant arrhythmias when sofosbuvir (in combination with daclatasvir or simeprevir) or ledipasvir/sofosbuvir is prescribed concurrently with amiodarone, and determine perceptions of co-medication frequency, reported changes in prescribing behaviour, and reported approaches to patient monitoring following dissemination of a direct healthcare professional communication.

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: 301 centres are involved in the study

Contact details

Study institution contact

Funmi Sserunkuma funmi.sserunkuma@gilead.com

Study contact

funmi.sserunkuma@gilead.com

Primary lead investigator

Funmi Sserunkuma

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 05/01/2016

Actual: 05/01/2016

Study start date

Planned: 01/12/2016

Actual: 25/11/2016

Data analysis start date
Planned: 15/03/2017

Actual: 10/03/2017

Date of final study report
Planned: 01/09/2017

Actual: 25/08/2017

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Gilead Sciences Europe

Study protocol

1.2-Prot GS-EU-337-2030 FINAL SIGNED.pdf(908.64 KB)

Regulatory

Was the study required by a regulatory body?

No

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:

The primary objective of this study is as follows: Determine the proportion of healthcare providers aware of the risk of clinically significant arrhythmias when SOF (in combination with DCV or SMV) or LDV/SOF is prescribed concurrently with amiodarone.

Study Design

Non-interventional study design

Cross-sectional

Study drug and medical condition

Name of medicine

HARVONI

SOVALDI

Medical condition to be studied

Chronic hepatitis C

Population studied

Short description of the study population

All healthcare providers (including gastroenterologists, hepatologists, infectious disease physicians, cardiologists, general practitioners/internists, and specialty and hospital pharmacists) responsible for the treatment of Chronic hepatitis C patients in Europe.

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

200

Study design details

Outcomes

The risk evaluation and mitigation strategy will be considered effective if the majority of respondents demonstrate they are aware of the key risks communicated.

Data analysis plan

Data from the survey questionnaire will be summarized descriptively (counts, ranges, proportions) overall, as well as by country and provider specialty where sample size allows. For the primary objective, frequency point-estimates with two-sided 95% confidence intervals(CIs) using the binomial distribution (Wald or Clopper-Pearson method, as appropriate) will be constructed to describe the proportion of physicians aware of the specified risk. The secondary objectives will produce categorical data which will be summarized by frequencydistributions.

Documents

Study results

GS-EU-337-2030+ABSTRACT+Clinical+Study+Report.pdf(102.32 KB)

Data management

Data sources

Data sources (types)

Other

Data sources (types), other

Survey involving primary 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