A Prospective cohort study on the use of Sofosbuvir-based regimens in HCV-infected patients in clinical practice in France (HELIOS)

First published: 24/09/2015

Last updated: 22/02/2024

Study Finalised

Administrative details

EU PAS number

EUPAS11074

Study ID

50593

DARWIN EU® study

No

Study countries

☐ France

Study description

GS-FR-334-1530: This was a multi-centre, prospective, non interventional cohort study. This study collected and evaluated information on safety and efficacy of sofosbuvir-based regimens in routine clinical practice in France.

Study status

Finalised

Research institutions and networks

Institutions

Gilead Sciences

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Institution | Pharmaceutical company

Multiple centres: 45 centres are involved in the study

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: 30/09/2014

Actual: 30/09/2014

Study start date

Planned: 05/10/2015

Actual: 13/10/2015

Data analysis start date

Planned: 30/11/2018

Actual: 23/04/2021

Date of final study report

Planned: 31/12/2021

Actual: 26/10/2022

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Gilead Sciences

Study protocol

GS-FR-334-1530 Protocol-5Dec2014 - Final.pdf(3.01 MB)

amd-2-prot-GS-FR-334-1530-09aug2017.pdf(2.27 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 topic:

Disease /health condition

Human medicinal product

Study type:

Non-interventional study

Scope of the study:

Effectiveness study (incl. comparative)

Safety study (incl. comparative)

Data collection methods:

Primary data collection

Main study objective:

The primary objective of this study was to assess the efficacy of sofosbuvir-based regimens in adult patients with chronic hepatitis C virus infection treated in routine clinical practice.

Study Design

Non-interventional study design

Cohort

Other

Non-interventional study design, other

Multi-centre, prospective, study

Study drug and medical condition

Medical condition to be studied

Chronic hepatitis C

Population studied

Short description of the study population

Adults patients aged 18 years or older with hepatitis C virus (HCV) infection received treatment with sofosbuvir, ledipasvir/sofosbuvir or sofosbuvir/velpatasvir in clinical practice in France.

Inclusion Criteria:

- Age ≥ 18 years
- HCV-infected patients (HCV RNA positive)
- Patient initiating treatment with Sofosbuvir*, Ledipasvir/Sofosbuvir* or Sofosbuvir/Velpatasvir*
- Signed Patient Information Form

* prescribed according to the respective SmPC

Exclusion Criteria:

- Concurrent participation in a HCV clinical trial (except trials not testing investigational medicinal product)
- Patients presenting a risk of not being able to be followed during 2 years (patients planning to move home, or leave the country in a foreseeable future)

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

Other

Special population of interest, other

Patients with hepatitis C virus infection

Estimated number of subjects

1031

Study design details

Outcomes

The proportion of subjects with sustained virologic response 12 weeks after discontinuation of therapy (SVR12). Rates of Adverse Drug Reaction, proportion of subjects with virologic response at 24 weeks post treatment, quality of life, patient adherence to HCV treatment, work productivity and activity Impairment, rate of consultations/hospitalizations due to HCV and/or liver disease and/or HCV treatment, treatment occurrence for anemia, thrombopenia and/or neutropenia

Data analysis plan

Descriptive analysis Binary, categorical and ordinal variables were described by counts and frequencies of each modality (over the total number of responses), and comparisons between groups were tested using chi square tests and/or Fisher’s exact tests. Continuous variables were described by means, standard errors, 95% confidence intervals, medians, minima, and maxima. Differences in means and medians between groups were tested using t-tests and non-parametric tests, respectively. When deemed necessary, sub-group comparisons and/or between time point comparisons may have been implemented. Multivariable analysis As part of the secondary objectives of this study, rates of events per person-time of exposure were computed using Poisson regression, after adjusting for potential confounding factors. These events included medication switching, medication discontinuation, co-

medication use, ADRs and SADRs and fatal AEs.

Documents

Study results

GS-FR-334-1530-CSR synopsis_f-redact.pdf(174.97 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

No