LICAVIR Study Synopsis and Table Shells

First published: 20/01/2022

Last updated: 14/03/2024

Study Finalised

Administrative details

EU PAS number

EUPAS44830

Study ID

44831

DARWIN EU® study

No

Study countries

☐ France

Study description

A retrospective data collection from a cohort of patients with chronic HCV infection, who developed HCC up to the end of 2019.

Study status

Finalised

Contact details

Study institution contact

Clinical Trial Disclosure AbbVie CT.Disclosures@abbvie.com

Study contact

CT.Disclosures@abbvie.com

Primary lead investigator

Clinical Trial Disclosure AbbVie

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 19/07/2021

Actual: 19/07/2021

Study start date

Planned: 19/07/2021

Actual: 19/07/2021

Date of final study report

Planned: 24/09/2021

Actual: 24/09/2021

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

AbbVie

Study protocol

20201014_Abbvie Licavir Synopsis_Final.pdf(245.05 KB)

Regulatory

Was the study required by a regulatory body?

No

Is the study required by a Risk Management Plan (RMP)?

Not applicable

Other study registration identification numbers and links

P21-900

Methodological aspects

Study type

Study type list

Study topic:

Disease /health condition

Human medicinal product

Study type:

Non-interventional study

Scope of the study:

Assessment of risk minimisation measure implementation or effectiveness

Data collection methods:

Secondary use of data

Main study objective:

To characterize the de novo HCC cases that occurred with and without DAA treatment.

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

Name of medicine

MAVIRET

Medical condition to be studied

Chronic hepatitis C

Population studied

Short description of the study population

Patients with chronic HCV infection, who developed HCC up to the end of 2019.

Age groups

Adults (46 to < 65 years)

Special population of interest

Hepatic impaired

Estimated number of subjects

397

Study design details

Data analysis plan

A descriptive analysis of patients treated with any DAA who develop HCC after DAA initiation and patients who develop HCC without DAA treatment. No direct comparisons of treatment groups will be performed. Summary statistics were provided as mean (SD) for continuous variables, for all individuals with non-missing values, and N (%) for categorical variables. Patient characteristics were assessed over the period from data start through 1 day prior to HCC diagnosis. For characteristics with multiple measurements or assessments (i.e. labs, fibrosis stage, etc.), the value closest but prior to HCC diagnosis was selected.

Documents

Study results

LICAVIR results abstract.pdf(128.38 KB)

Data management

Data sources

Data sources (types)

Other

Data sources (types), other

Retrospective 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