Direct-acting antivirals (DAAs) for the treatment of chronic hepatitis C virus (HCV) infection and the risk of hepatocellular carcinoma (HCC) recurrence: A protocol for a systematic literature review

First published: 18/06/2021

Last updated: 23/02/2022

Study Finalised

Administrative details

EU PAS number

EUPAS41657

Study ID

45930

DARWIN EU® study

No

Study countries

☐ United States

Study description

A systematic literature review (SLR) will be conducted to identify and synthesize the evidence from the peer-reviewed published literature on the risk of early HCC recurrence following DAA therapy for chronic HCV infection. The mechanisms and rate of HCC recurrence after DAA treatment are unknown and there is conflicting evidence in the published literature. Following Cochrane, PRISMA 2020, and EMA recommended methodologies, the SLR will provide results among a well-characterized group of adult patients who were treated with DAA therapy for chronic HCV, relative to no DAA therapy, after successful HCC treatment.

Study status

Finalised

Research institutions and networks

Institutions

IQVIA

United Kingdom

First published: 12/11/2021

Last updated: 22/04/2024

Institution **Non-Pharmaceutical company** **ENCePP partner**

Contact details

Study institution contact

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Study contact

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Primary lead investigator

Jennifer Uyei

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 29/04/2021

Actual: 29/04/2021

Study start date

Planned: 14/06/2021

Actual: 21/06/2021

Data analysis start date

Planned: 05/07/2021

Actual: 23/08/2021

Date of final study report

Planned: 28/02/2022

Actual: 22/02/2022

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

MAHs of the DAAs Consortium (AbbVie Inc., Gilead Sciences, Inc., and Merck Sharp & Dohme Corp.)

Study protocol

DAA_Consortium-IQVIA SLR Protocol - EU PAS.pdf(6.15 MB)

Regulatory

Was the study required by a regulatory body?

Yes

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

Not applicable

Methodological aspects

Study type

Study type list

Study topic:

Human medicinal product

Disease /health condition

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:

The objective of the systematic review is to estimate the comparative risk of early HCC recurrence in individuals who were successfully treated for HCC and subsequently treated with DAAs versus not treated with DAAs for chronic HCV. A meta-analysis of the main outcomes will be performed if the data are available.

Study Design

Non-interventional study design

Systematic review and meta-analysis

Study drug and medical condition

Anatomical Therapeutic Chemical (ATC) code

(J05AP) Antivirals for treatment of HCV infections

Antivirals for treatment of HCV infections

Medical condition to be studied

Chronic hepatitis C

Hepatocellular carcinoma

Population studied

Short description of the study population

Adult patients who were treated with DAA therapy for chronic HCV.

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

1000

Study design details

Outcomes

Risk of early HCC recurrence (proportion or percentage, relative risk or risk ratio), Incidence of HCC recurrence (rate or hazard/rate ratio)

Data analysis plan

Pairwise meta-analysis with subgroup and sensitivity analyses if deemed feasible

Documents

Study results

Hep C Consortium-IQVIA_DAA for HCV and risk of HCC_Abstract-EU PAS.pdf (193.5 KB)

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

Systematic review of the literature, including comparative clinical trials and observational/real-world studies published in full-text journal articles, conference abstracts, or registry databases.

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