DAA-PASS: A Post-Authorisation Safety Study of Early Recurrence of Hepatocellular Carcinoma in HCV-Infected Patients after Direct-Acting Antiviral Therapy

First published: 01/03/2018

Last updated: 23/04/2024

Study | Finalised

Administrative details

EU PAS number

EUPAS22896

Study ID

47600

DARWIN EU® study

No

Study countries

France

Germany

Italy

Spain

United States

Study description

This prospective, observational study will estimate the risk of early HCC recurrence associated with DAA therapy exposure relative to no DAA therapy exposure during routine clinical care of HCV-infected patients with previous successfully treated HCC using a prospective cohort from TARGET HCC.

Study status

Finalised

Research institutions and networks

Institutions

Multiple centres: 60 centres are involved in the study

Contact details

Study institution contact

Andrea Mospan amospan@targetpharmasolutions.com

Study contact

amospan@targetpharmasolutions.com

Primary lead investigator

Andrea Mospan

Primary lead investigator

Study timelines

Date when funding contract was signed
Planned: 12/02/2018

Actual: 12/02/2018

Study start date
Planned: 05/03/2018

Actual: 29/03/2018

Date of final study report
Planned: 31/12/2021

Actual: 15/12/2021

Sources of funding

- Other

More details on funding

TARGET PharmaSolutions, Inc.

Study protocol

TARGET-HCC_DAA-PASS_Protocol_v3_3_06Jun2018_Final.pdf (967.39 KB)

TARGET-HCC_DAA-PASS_Protocol_v6.0.pdf (1.26 MB)

Regulatory

Was the study required by a regulatory body?

Yes

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

EU RMP category 1 (imposed as condition of marketing authorisation)

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:

Estimate the risk of early HCC recurrence associated with DAA therapy exposure relative to no DAA therapy exposure in the prospective DAA-PASS

cohort.

Study Design

Non-interventional study design

Other

Non-interventional study design, other

Observational study

Study drug and medical condition

Study drug International non-proprietary name (INN) or common name

SOFOSBUVIR

VELPATASVIR

VOXILAPREVIR

ELBASVIR

GRAZOPREVIR

GLECAPREVIR

PIBRENTASVIR

Anatomical Therapeutic Chemical (ATC) code

(J05AX14) daclatasvir

daclatasvir

(J05AX16) dasabuvir

dasabuvir

(J05AX67) ombitasvir, paritaprevir and ritonavir

ombitasvir, paritaprevir and ritonavir

(J05AE14) simeprevir

simeprevir

(J05AX15) sofosbuvir

sofosbuvir

(J05AX65) sofosbuvir and ledipasvir

sofosbuvir and ledipasvir

(J05AX69) sofosbuvir and velpatasvir

sofosbuvir and velpatasvir

Medical condition to be studied

Hepatocellular carcinoma

Population studied

Short description of the study population

Prospective Cohort

The prospective DAA-PASS cohort will include a subset of HCV RNA positive participants in the TARGET-HCC study who meet entry criteria including hepatitis C (with no prior history of DAA therapy) and newly diagnosed Barcelona Clinic Liver Cancer (BCLC) Stage A HCC. Participants will be enrolled in the countries participating in TARGET-HCC which will include the United States (US), France, Germany, Italy, and Spain.

Historical Cohort

The historical cohort will be derived from the ITA.LI.CA database, which includes data on all consecutive patients with HCC who were managed within participating centers in Italy. The historical cohort will include patients from the ITA.LI.CA database who have active HCV infection who were not treated for HCV (IFN-based or DAA-based regimens) during the followup period, with initial HCC

diagnosis BCLC Stage A, and subsequent successful treatment of HCC with curative therapy.

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

35

Study design details

Outcomes

Time to recurrence of HCC, A. Number of events (early HCC recurrence)

Data analysis plan

risk estimation

Documents

Study results

DAA-PASS CSR Abstract 2.0_Final_Redacted.pdf (468.72 KB)

DAA-PASS CSR Abstract Final v5.0_ 16 Dec 2021.pdf (92.22 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

TARGET-HCC

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