DARWIN EU® Characterization of patients with chronic hepatitis B and C

First published: 28/11/2023

Last updated: 20/08/2026

Study Finalised

Administrative details

EU PAS number

EUPAS107650

Study ID

107783

DARWIN EU® study

Yes

Study countries

- Estonia
- France
- Germany
- Netherlands
- Spain
- United Kingdom

Study description

Sustainable Development Goals for 2030 set by UN Member States include Target 3.3 states, calling for an end to epidemics of AIDS, tuberculosis, malaria and neglected tropical diseases and combat hepatitis, water-borne diseases and other communicable diseases. The 2016 WHO Global Health Sector Strategy (GHSS) aims to eliminate viral hepatitis by 2030, and WHO EU has developed a hepatitis action plan to steer the implementation of the GHSS in Europe. The European Centre for Disease Prevention and Control (ECDC) has developed a monitoring system for Hepatitis B Viral Infection (HBV) and Hepatitis C Viral Infection (HCV) aligned with indicators and targets of the GHSS and the WHO European Region Action Plan. Comprehensive data on the prevalence of chronic HBV or HCV infections and utilisation of antiviral treatments for chronic HBV or HCV infections are important to monitor progress towards the elimination targets related to treatment, to adjust prevalence estimates over time, and to support effective planning of prevention and control activities by countries. This DARWIN EU imitative aims to provide robust and timely data at national or subnational level. The aims are to report the number and percentage of patients diagnosed with chronic HBV or HCV infection who initiate or undergo treatment with interferon or any specified antivirals, to characterize patients with chronic HBV or HCV infection at the initiation of treatment with interferon or specified antivirals and to estimate the proportion of all patients with chronic HBV or HCV infection. All the analyses will be stratified by age, sex, calendar year, and database during the study period 2012 to 2022.

Study status

Finalised

Research institutions and networks

Networks

Data Analysis and Real World Interrogation Network (DARWIN EU®)

- Belgium
- Croatia
- Denmark
- Estonia
- Finland
- France
- Germany
- Greece
- Hungary
- Italy
- Lithuania
- Netherlands
- Norway
- Poland
- Portugal
- Spain
- Sweden
- United Kingdom
- United States

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Network

Contact details

Study institution contact

Ilse Schuemie study@darwin-eu.org

Study contact

study@darwin-eu.org

Primary lead investigator

Katia Verhamme

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 30/08/2023

Actual: 30/08/2023

Study start date

Planned: 30/08/2023

Actual: 30/08/2023

Date of final study report

Planned: 18/12/2023

Actual: 16/02/2024

Sources of funding

- EMA

Study protocol

DARWIN EU_D2.2.3_Protocol_P2-C1-010_HBV_HCV_Pts_Characterisation_v2.1.pdf (951.11 KB)

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:

Disease /health condition

Study type:

Non-interventional study

Scope of the study:

Disease epidemiology

Drug utilisation

Data collection methods:

Secondary use of data

Study design:

• Population-level drug utilisation study

• New drug user cohort study (Objective 3)

• Population-level cohort study (Objective 4)

Main study objective:

To estimate the number and percentage of individuals initiating or undergoing treatment with interferon or any of the specific antivirals of interests among patients with chronic HBV HCV infection, stratified by age, sex, calendar year and country/database during the study period.

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

Anatomical Therapeutic Chemical (ATC) code

(J05AP) Antivirals for treatment of HCV infections

Antivirals for treatment of HCV infections

(L03AB61) peginterferon alfa-2a, combinations

peginterferon alfa-2a, combinations

Medical condition to be studied

Chronic hepatitis B

Population studied

Short description of the study population

For population-level drug utilization (Objective 1 and 2), the study population included all patients with chronic HBV or chronic HCV infection in the respective databases from 2012 to 2022 (or the latest available date if earlier).
For patient-level drug utilization (Objective 3), the study population included all patients with chronic HBV or
chronic HCV infection who were new users of interferon or any of the specific antivirals of interests in the respective databases from 2012 to 2022 (or the latest available date if earlier), and no record of using the
respective drugs in the year preceding the index date.
For population-level descriptive epidemiology (Objective 4), the study population included all individuals
identified in the database from 2012 to 2022.

Age groups

- Preterm newborn infants (0 – 27 days)
- Term newborn infants (0 – 27 days)
- Infants and toddlers (28 days – 23 months)
- Children (2 to < 12 years)
- Adolescents (12 to < 18 years)
- 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)

Estimated number of subjects

15.800.000

Study design details

Setting

Inpatient and outpatient setting using data from the following 6 data sources: CHUBX (France), CPRD GOLD (UK), EBB (Estonia), IQVIA DA Germany (Germany), IMASIS (Spain) and IPCI (the Netherlands).

Data analysis plan

Analyses will be conducted separately for each database. Before study initiation, test runs of the analytics are performed on a subset of the data sources or on a simulated set of patients and quality control checks are performed. Once all the tests are passed, the final package is released in the version-controlled Study Repository for execution against all the participating data sources. The data partners locally execute the analytics against the OMOP CDM in R Studio and review and approve the by default aggregated results before returning them to the Coordination Centre. Sometimes multiple execution iterations are performed, and additional fine tuning of the code base is needed. A service desk will be available during the study execution for support. The study results of all data sources are checked after which they are made available to the team in the Digital Research Environment DRE and the Study Dissemination Phase can start. All results are locked and timestamped for repro.

Summary results

CONCLUSION

Patients diagnosed with chronic HBV and HCV infections typically belong to the middle-aged adult demographic, with a male predominance and often presenting with comorbidities such as hypertension and diabetes mellitus. Across various databases (excluding EBB, where nearly half of HCV patients received treatment), fewer than 15% of diagnosed patients underwent treatment with interferon or antiviral medications with large variations between databases. Common treatments included entecavir, tenofovir disoproxil, and peginterferon alfa-2a for chronic HBV infection, while chronic HCV infection was frequently managed with glecaprevir, ledipasvir/sofosbuvir, ribavirin, sofosbuvir, and sofosbuvir/velpatasvir. The proportion of patients chronic HBV and HCV infections remained low in the study population.

Documents

Study report

DARWIN EU_D2.2.4_Report_P2-C1-010_HBV_HCV_Pts_Characterisation_v2.1.pdf (2.12 MB)

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 source(s)

Institut Municipal d'Assistència Sanitària Information System / Hospital del Mar / PSMAR / (Hospital del Mar Information System)

Integrated Primary Care Information (IPCI)

Clinical Practice Research Datalink (CPRD) GOLD

Estonian Biobank

IQVIA Disease Analyzer Germany

Clinical Data Warehouse of the Bordeaux University Hospital

Data sources (types)

Administrative healthcare records (e.g., claims)

Electronic healthcare records (EHR)

Use of a Common Data Model (CDM)

CDM mapping

Yes

CDM Mappings

CDM name

OMOP

CDM website

https://www.ohdsi.org/Data-standardization/

Data quality specifications

Check conformance

Unknown

Check completeness

Unknown

Check stability

Unknown

Check logical consistency

Unknown

Data characterisation

Data characterisation conducted

No