The European HBV Registry: A joint initiative of TherVacB and DZIF (HBV Registry)

First published: 03/09/2021

Last updated: 25/03/2025

Study Ongoing

Administrative details

EU PAS number

EUPAS42767

Study ID

49036

DARWIN EU® study

No

Study countries

- ☐ Germany
- ☐ Italy
- ☐ Spain
- ☐ United Kingdom

Study description

In order to tackle the unmet needs in chronic HBV infection, a consortium of clinical partners has gathered to establish a registry for patients with hepatitis B mono- and co-infections.

The partners will build up a European-wide registry to be able to stratify patients for upcoming clinical trials. Extensive analyses of virus and host-specific parameters are to be carried out from these patients.

The knowledge gained thereby should contribute to a better understanding of the HBV control and enable patient stratification with regard to immunomodulatory therapies.

Furthermore, hepatitis B patients are to be identified who are willing to participate in future studies to investigate immunotherapies to cure HBV infections (e.g. therapeutic vaccines).

Study status

Ongoing

Research institutions and networks

Institutions

Hannover Medical School (MHH)

First published: 01/02/2024

Last updated: 01/02/2024

Institution | Educational Institution | Hospital/Clinic/Other health care facility

UKE Hamburg, Germany, TUM-MRI Munich, Germany, UK Leipzig Leipzig, Germany, FCRB Barcelona, Spain, AOP Parma, Italy, RFH London, UK, BLT London, UK

Networks

TherVacB, DZIF

Contact details

Study institution contact

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Primary lead investigator

Markus Cornberg

Primary lead investigator

Study timelines

Date when funding contract was signed

Actual: 01/01/2020

Study start date
Actual: 06/05/2021

Date of final study report
Planned: 31/12/2026

Sources of funding

- EU institutional research programme
- Other

More details on funding

BMBF, Horizon 2020

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:

Other

Study type:

Non-interventional study

Scope of the study:

Other

If ‘other’, further details on the scope of the study

Establishment and immunological characterisation of a patient cohort and associated viral markers

Main study objective:

Characterization of viral and immunological markers in hepatitis B patients. The knowledge gained should contribute to a better understanding of HBV control and enable patient stratification with regard to immunomodulatory therapies.

Study Design

Non-interventional study design

Cohort

Population studied

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)

Estimated number of subjects

3000

Study design details

Outcomes

HBsAg decline/loss, seroconversion to anti-HBs, Quantification of soluble immune mediators, Hepatitis B related Quality of Life (SF36), hepatocellular carcinoma (HCC), liver cirrhosis, death

Data analysis plan

Quantification and characterization of viral markers and immunological patient markers.

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)

The European HBV Registry - A joint initiative of TherVacB and DZIF

Data sources (types)

Disease registry

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