A retrospective data collection to increase the knowledge base of posttransplant treatment with the human hepatitis B immunoglobulin Zutectra or Hepatect CP in liver transplanted patients (Hepatect CP / Zutectra RDC)

First published: 25/11/2014

Last updated: 01/04/2024

Study Finalised

Administrative details

EU PAS number

EUPAS8028

Study ID

25888

DARWIN EU® study

No

Study countries

- [ ] Germany
- [ ] Italy
- [ ] Netherlands
- [ ] Switzerland
- [ ] United Kingdom

Study description

RDC Objectives• The effectiveness of long-term protection from HBV-recurrence after liver transplantation (LT) using subcutaneous Zutectra® or iv Hepatect® CP and / or a further hepatitis B immunoglobulin (HBIg) in the same patient. • If HBV-HCC (hepatocellular carcinoma) is the reason for LT or HBV-HCC is detected in the explanted liver the rate of HBV-HCC recurrence. RDC DesignRetrospective, non-interventional, uncontrolled, single-arm, international, multi-centre, post-approvalRDC PopulationMale and female adult patients after LT for HBV-induced liver failure

Study status

Finalised

Research institutions and networks

Institutions

Beckebaum

Multiple centres: 20 centres are involved in the study

Contact details

Study institution contact

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Study contact

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Primary lead investigator

Susanne Beckebaum

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 18/12/2014

Actual: 09/12/2014

Study start date

Planned: 19/01/2015

Actual: 19/01/2015

Data analysis start date

Planned: 01/07/2016

Date of final study report

Planned: 31/12/2016

Actual: 24/05/2017

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Biotest AG

Regulatory

Was the study required by a regulatory body?

No

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

Non-EU RMP only

Methodological aspects

Study type

Study type list

Study topic:

Disease /health condition

Human medicinal product

Study type:

Non-interventional study

Scope of the study:

Effectiveness study (incl. comparative)

Data collection methods:

Secondary use of data

Main study objective:

The effectiveness of long-term protection from HBV-recurrence after liver transplantation (LT) using subcutaneous Zutectra® or iv Hepatect® CP and / or a further hepatitis B immunoglobulin (HBIg) in the same patient.

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

Medicinal product name

ZUTECTRA

Medicinal product name, other

Hepatect CP

Medical condition to be studied

Liver transplant

Population studied

Short description of the study population

Male and female adult patients after liver transplantation (LT) for hepatitis B virus (HBV)-induced liver failure.

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

Immunocompromised

Estimated number of subjects

400

Study design details

Outcomes

HBV-recurrence after liver transplantation, HBV-HCC (hepatocellular carcinoma) recurrence after liver transplantation

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Data analysis plan

Descriptive statisticsProportion and absolute number of HBV-liver transplant patients free of hepatitis B virus recurrence as assessed by non-detectability of HBsAg and / or HBV-DNA in patients' sera.The rate of HBV-HCC recurrence, if HBV-HCC is the reason for LT or HBV-HCC is detected in the explanted liver.

Data management

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

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