Real Life, Long-term Effectiveness and Safety of Zutectra Self-Administration for HBV Re-Infection Prophylaxis after Liver Transplantation in France and Spain (Zutectra NIS)

First published: 03/12/2014

Last updated: 06/03/2024

Study Finalised

Administrative details

EU PAS number

EUPAS8116

Study ID

27428

DARWIN EU® study

No

Study countries

- ☐ France
- ☐ Spain

Study description

Prospective documentation of long-term effectiveness, safety, convenience and patient adherence to Zutectra® subcutaneous self-administration for protection from HBV-recurrence after liver transplantation (LT) aiming at confirmation of existing data under real life conditions.

Study status

Finalised

Research institutions and networks

Institutions

Biotest

First published: 01/02/2024

Last updated: 01/02/2024

Institution

Multiple centres: 18 centres are involved in the study

Contact details

Study institution contact

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Study contact

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Primary lead investigator

Didier Samuel

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 12/01/2015

Actual: 01/01/2015

Study start date

Planned: 01/06/2015

Actual: 01/06/2015

Data analysis start date

Planned: 30/09/2020

Date of final study report

Planned: 31/12/2020

Actual: 17/06/2021

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)?

Not applicable

Methodological aspects

Study type

Study type list

Study topic:

Disease /health condition

Human medicinal product

Study type:

Non-interventional study

Scope of the study:

Assessment of risk minimisation measure implementation or effectiveness

Effectiveness study (incl. comparative)

Safety study (incl. comparative)

Data collection methods:

Secondary use of data

Main study objective:

Determination of the number of patients with at least one hepatitis B related recurrence as assessed by detection of HBsAg (HBsAg positive) and/or HBV-DNA
The determination of the number and nature of adverse events (AEs) including relatedness to Zutectra

Study Design

Non-interventional study design

Cohort

Other

Non-interventional study design, other

Prospective, single-arm, multicentre, international post-approval study

Study drug and medical condition

Name of medicine

ZUTECTRA

Medical condition to be studied

Liver transplant

Population studied

Short description of the study population

The study population involved 18 years or older aged patients with liver transplant (LT) received treatment with Zutectra.

Inclusion criteria:

1. Patients 18 years or older.

2. Patients with LT for fluminant hepatitis B, hepatitis B- cirrhosis, HBV-induced HBV-HCC, or with liver re-transplantation except due to HBV recurrence.

3. Subjects under Zutectra treatment without or with a virostatic treatment.

4. Written informed consent to allow data collection and data transfer to third party.

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

200

Study design details

Outcomes

Proportion and absolute number of patients with at least one hepatitis B related recurrence as assessed by detection of HBsAg (HBsAg positive) and/or HBV-DNA

Number and nature of adverse events (AEs) including relatedness to Zutectra, The achieved mean serum HBIg trough levels under Zutectra treatment as determined at clinical visits. Safety laboratory parameters like liver and kidney function. Compliance: Adherence to the sc treatment with Zutectra. Patient satisfaction and quality of life.

Data analysis plan

All analyses will be performed in an exploratory sense. Since there are no confirmatory analyses planned, hypotheses are not formulated. Data will be analysed using descriptive statistics.

Documents

Study results

NIS Zutectra_study report_final_2021-06-17 - blinded.pdf(1.13 MB)

Data management

Data sources

Data sources (types)

Electronic healthcare records (EHR)

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