Non-interventional study (NIS) for long-term monitoring of the treatment of hemophilia A with Haemoctin SDH (Haemoctin NIS)

First published: 27/11/2014

Last updated: 01/04/2024

Study | Finalised

Administrative details

EU PAS number

EUPAS8063

Study ID

25885

DARWIN EU® study

No

Study countries

Germany

Hungary

Study description

With the present NIS data on effectiveness, tolerability and safety of the drug in the long-term treatment under real life conditions will be documented.The following questions should be considered:What impact has a treatment with Haemoctin over many years to decades on the health of patients?Can the risk of bleeding for years to be effectively reduced?What is the risk for inhibitor formation during treatment with Haemoctin SDH in previous treated and untreated patients?A signal from pharmacovigilance, which would make this investigation mandatory, is not evident.

Study status

Finalised

Research institutions and networks

Institutions

Dr. Christoph Königs

Multiple centres: 20 centres are involved in the study

Contact details

Study institution contact

Artur Bauhofer artur_bauhofer@biotest.de

Study contact

artur_bauhofer@biotest.de

Primary lead investigator

Christoph Königs

Primary lead investigator

Study timelines

Date when funding contract was signed
Actual: 01/05/1998

Study start date
Actual: 29/05/1998

Data analysis start date
Planned: 01/07/2016

Date of interim report, if expected
Actual: 30/07/2010

Date of final study report
Planned: 31/12/2016

Actual: 13/04/2017

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:

Assessment of risk minimisation measure implementation or effectiveness

Effectiveness study (incl. comparative)

Data collection methods:

Primary data collection

Main study objective:

With the present NIS data on effectiveness, tolerability and safety of the drug in the long-term treatment under real life conditions will be documented.

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

Medicinal product name, other

Haemoctin SDH

Medical condition to be studied

Factor VIII deficiency

Population studied

Short description of the study population

Hemophilia A patients treated with Haemoctin SDH.

Age groups

- 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)

Special population of interest

Other

Special population of interest, other

Hemophilia A patients

Estimated number of subjects

300

Study design details

Data analysis plan

Descriptive statistics will be applied for analysis of effectiveness and safety data.

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

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

Unknown