Haemonine - Post marketing study for long-term treatment of Haemophilia B patients (NIS Haemonine)

First published: 27/11/2014

Last updated: 06/03/2024

Study Finalised

Administrative details

PURI

https://redirect.ema.europa.eu/resource/33097

EU PAS number

EUPAS8060

Study ID

33097

DARWIN EU® study

No

Study countries

☐ Germany

Study description

The post marketing study (PMS) aims to enhance knowledge on the safety profile and effectiveness of Haemonine in the long-term treatment of Haemophilia B patients. Based on the developmental data, there is no particular safety concern for Haemonine. It is expected that the existing safety profile is confirmed by the collection of real life data derived from this study.

Study status

Finalised

Research institutions and networks

Institutions

Biotest

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Institution

Multiple centres: 10 centres are involved in the study

Contact details

Study institution contact

Artur Bauhofer

Study contact

artur.bauhofer@biotest.com

Primary lead investigator

Christoph Königs

Primary lead investigator

Study timelines

Date when funding contract was signed

Actual: 05/11/2009

Study start date

Actual: 07/12/2009

Data analysis start date

Planned: 30/06/2019

Actual: 30/06/2019

Date of interim report, if expected

Actual: 23/07/2014

Date of final study report

Planned: 31/12/2019

Actual: 12/08/2019

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

Disease epidemiology

Effectiveness study (incl. comparative)

Data collection methods:

Primary data collection

Main study objective:

Determination of the incidence and nature of adverse events and of the effectiveness of Haemonine

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

Name of medicine, other

Haemonine

Medical condition to be studied

Coagulation factor deficiency

Population studied

Short description of the study population

Haemophilia B patients.

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

Haemophilia B patients

Estimated number of subjects

50

Study design details

Data analysis plan

Factor IX consumption, overall assessment on efficacy and ease of use, incidence and nature of adverse events

Data management

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

No