# Non-interventional study of long term treatment with Haemoctin SDH (Biotest NIS-016)

**First published:** 08/06/2016

**Last updated:** 02/07/2024

Study Finalised

## Administrative details

**PURI**

https://redirect.ema.europa.eu/resource/27437

**EU PAS number**

EUPAS13728

**Study ID**

27437

**DARWIN EU® study**

No

**Study countries**

☐ Australia

☐ Germany

☐ Hungary

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**Study description**

Haemoctin SDH is a factor VIII (FVIII) preparation derived from human plasma purified by chromatography. Haemoctin SDH is approved for prevention and treatment of innate and acquired factor VIII deficiencies. Also, patients with a FVIII inhibitor can be treated with Haemoctin SDH. Details are given in the SPC of Haemoctin SDH. The stabilization of the FVIII molecule is carried out by the natural carrier protein von Willebrand factor. There is no need for the addition of auxiliary stabilizers such as sucrose or human serum albumin. Hemophilia A is an inherited, chronic bleeding disorder and patients have to be treated lifelong with FVIII concentrates. Most children and adolescents are treated prophylactically in industrialized countries. Prophylaxis has the goal to avoid bleedings, in order to guarantee the patient a high quality of life (QoL). Patients who have started in childhood with the prophylaxis, this treatment is extended in adulthood. Prophylactic treatment consists of regular FVIII applications, usually three times a week. With this study long-term data will be generated. Unique longterm data obtained form some patients in a previous study with Haemoctin SDH over up to 22 year can be extended with this study. This NIS allows adopting the documentation to the current guidance for observational studies and adjusted focus of the objectives.

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**Study status**

Finalised

# Research institutions and networks

## Institutions

# Biotest

**First published:** 01/02/2024

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Institution

## Contact details

### Study institution contact

Artur Bauhofer

Study contact

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### Primary lead investigator

Christoph Königs

Primary lead investigator

## Study timelines

### Date when funding contract was signed

Planned: 01/02/2016

Actual: 12/04/2016

### Study start date

Planned: 01/03/2016

Actual: 01/06/2016

**Data analysis start date**
Planned: 31/12/2021

Actual: 01/01/2023

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**Date of final study report**
Planned: 30/09/2023

Actual: 08/12/2023

## Sources of funding

- Pharmaceutical company and other private sector

## More details on funding

Biotest AG

## Study protocol

2021-02-18 Haemoctin NIS Observation Plan_V2 clean.pdf(192.41 KB)

## Regulatory

**Was the study required by a regulatory body?**

No

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

Not applicable

# Methodological aspects

## Study type

## Study type list

**Study type:**

Non-interventional study

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**Scope of the study:**

Drug utilisation

Effectiveness study (incl. comparative)

**Main study objective:**

With this NIS long-term data for the effectiveness in bleedingprevention and on QoL will be generated.The following questions will be examined:· What are the factors influencing the risk of bleeding over thetime of treatment?· What are the factors influencing the risk to develop FVIIIinhibitors during treatment with Haemoctin SDH?· Can these inhibitors be further characterized?

## Study Design

**Non-interventional study design**

Other

## Study drug and medical condition

**Name of medicine, other**

Haemoctin SDH

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**Medical condition to be studied**

Factor VIII deficiency

## Population studied

**Age groups**

Term newborn infants (0 – 27 days)

Infants and toddlers (28 days – 23 months)

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)

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**Special population of interest**

Immunocompromised

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**Estimated number of subjects**

150

## Study design details

**Outcomes**

Annual bleeding rate defined as episodes per year in patients with Haemoctin SDH treatment, differentiated by prophylaxis and on demand Treatment. · AE and subsequent suspected ADR (AE assessed as causally related with Haemoctin treatment) · AE with bleeding = AE of special interest (AESI) with extended bleeding documentation, for e.g. if the duration and severity of the bleeding is within the situation as expected or unexpected · characterization of FVIII inhibitors to Haemoctin SDH · QoL determined with the EQ-5D

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**Data analysis plan**

All analyses will be performed in an exploratory sense. Data will be analyzed using descriptive statistics. For continuous variables, mean, standard deviation, minimum, maximum, median, 25% and 75% percentiles will be presented. Qualitative and categorical variables will be presented by means of absolute and relative frequencies. A medical evaluation of the findings will be performed. Details of analysis will be described in a statistical analysis plan.

## Documents

**Study results**

BT13218_CSR_Final_v1.0_20231208_Redacted.pdf(2.9 MB)

# 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