Evaluation of the Effectiveness of Risk Minimisation Measures: A Survey among Health Care Professionals to Assess their Knowledge on Dosing and Administration of Obizur® (Susoctocog alfa) in 6 European Countries

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Last updated: 04/08/2022

Study Finalised

Administrative details

EU PAS number

EUPAS29813

Study ID

48511

DARWIN EU® study

No

Study countries

Belgium

Germany

Italy

Netherlands

Sweden

United Kingdom

Study description

Obizur® (susoctocog alfa) is indicated in adults for treatment of bleeding episodes in patients with acquired haemophilia caused by antibodies to Factor VIII (AHA). The overall research question is to evaluate whether healthcare professionals (HCPs) expected to prescribe or dispense Obizur have been successfully informed by the educational materials regarding the method of calculation and administration of Obizur. Study design: This is a cross-sectional, multinational web based survey conducted in 6 selected European countries (Belgium, Germany, Italy, Netherlands, Sweden, UK) among HCPs who treat patients with AHA and may be involved in prescribing, dose calculation, and dispensing of Obizur and were targeted to receive the educational materials. Population The study will be conducted among HCPs (physicians, nurses, pharmacists) who treat patients with AHA or may be involved in dose calculation or dispensing of Obizur. Data Sources The survey will involve primary data collection conducted through web questionnaire or phone. In order to address the study objectives, the following information will be collected: • Information on participating HCPs (demographics, HCP subgroup, specialty, setting) • Information on participating HCPs' awareness of the educational materials (recollecting receiving the educational materials, awareness of content, knowledge of content) • For HCPs who have prescribed, calculated the dose of, or dispensed Obizur: information on patients (characteristics, administered and calculated dose, reasons for deviations from recommended dose). Study Size The target sample size for this study is 100 HCPs. Such a

sample would allow the description of an unknown proportion of correct answers to any of the survey questions with a precision of 9.8% for a 95% confidence interval. Achievement of the sample size will depend on the number of HCPs who have received the educational materials.

Study status

Finalised

Research institutions and networks

Institutions

IQVIA

United Kingdom

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Institution | Non-Pharmaceutical company | ENCePP partner

Contact details

Study institution contact

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Primary lead investigator

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Primary lead investigator

Study timelines

Date when funding contract was signed
Planned: 15/12/2017

Actual: 15/12/2017

Study start date
Planned: 01/07/2019

Actual: 30/09/2019

Data analysis start date
Planned: 15/01/2020

Actual: 26/11/2019

Date of final study report
Planned: 31/03/2020

Actual: 06/03/2020

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Takeda

Regulatory

Was the study required by a regulatory body?

No

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

EU RMP category 3 (required)

Methodological aspects

Study type

Study type list

Study topic:

Human medicinal product

Study type:

Non-interventional study

Scope of the study:

Effectiveness study (incl. comparative)

Data collection methods:

Primary data collection

Main study objective:

The overall research question is to evaluate whether healthcare professionals expected to prescribe or dispense Obizur have been successfully informed by the educational materials regarding the method of calculation and

administration of Obizur.

Study Design

Non-interventional study design

Cross-sectional

Other

Non-interventional study design, other

Multinational web based survey

Study drug and medical condition

Medicinal product name

OBIZUR

Population studied

Short description of the study population

A survey of healthcare professionals (HCPs) who treated patients with acquired haemophilia caused by antibodies to Factor VIII (AHA) by prescribing Obizur® (susoctocog alfa) in 6 selected European countries (Belgium, Germany, Italy, Netherlands, Sweden, UK).

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)

Estimated number of subjects

100

Study design details

Outcomes

Success rates will be determined: Success if o Proportion of HCPs remembering having received the educational materials ≥60% AND o ≥80% of HCPs knowledgeable of the educational materials content AND o Proportion of HCPs who would or did prescribe, calculate the dose of, or dispense Obizur in line with the educational materials ≥60%, Success, if •≥70% of HCPs remember having received the EM • ≥70% HCPs are knowledgeable about the content of the EM Success, if •≥70%HCPs would prescribe, calculate the dose of, or dispense Obizur in line with the EM messages •≥80% of HCPs did prescribe, calculate the dose of, or dispense Obizur in line with the EM by collecting self-reported dosing and dispensing information

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Data analysis plan

Descriptive statistics will be applied. The endpoints will be assessed in overall, by country, and among different types of HCPs (physicians, pharmacists, nurses). Analyses by country will be performed in case if the number of HCPs per country will be >15. Continuous variables will be described by their number (of valid cases, of missing values), mean, standard deviation, and median, Q1, Q3, minimum and maximum. Categorical variables will be described as the total number and relative percentage per category. These will be the percentage per

category. Confidence intervals of 95% will be evaluated, when relevant. The proportions of correct and appropriate answers to selected questions asked in the questionnaire will be expressed among HCPs who provided answers to those questions .

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

Survey of health care professionals, the number entered refers to the number of health care professionals, not to the number of patients

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