A Multinational Phase IV Study Evaluating “Real World” Treatment Pattern in Previously Treated Hemophilia A Patients Receiving KOVALTRY (Octocog alfa) for Routine Prophylaxis (TAURUS)

First published: 26/09/2016

Last updated: 01/04/2024

Study Finalised

Administrative details

EU PAS number

EUPAS15459

Study ID

44492

DARWIN EU® study

No

Study countries

Belgium

Canada

- Colombia
- France
- Germany
- Greece
- Italy
- Luxembourg
- Netherlands
- Slovenia
- Spain
- Taiwan
- United States

Study description

The primary objective of this study is to investigate weekly prophylaxis dosing regimens used in standard clinical practice. In addition the study will capture reported bleed rate, pattern of change in KOVALTRY prophylaxis dose & dosing frequency, reason for choice of treatment regimen, FVIII product switch pattern, patient treatment satisfaction and adherence, KOVALTRY pharmacokinetic data (if performed), KOVALTRY consumption, as well as safety data.

Study status

Finalised

Research institutions and networks

Institutions

Bayer AG

First published: 01/02/2024

Last updated: 01/02/2024

Institution

Multiple centres: 100 centres are involved in the study

Contact details

Study institution contact

Bayer Clinical Trials Contact Bayer AG clinical-trials-contact@bayer.com

Study contact

clinical-trials-contact@bayer.com

Primary lead investigator

Bayer Clinical Trials Contact Bayer AG

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 01/03/2016

Actual: 04/03/2016

Study start date
Planned: 01/09/2016

Actual: 14/10/2016

Date of final study report
Planned: 30/12/2022

Actual: 31/08/2021

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Bayer

Study protocol

TAURUS_18559_protocol_cor Logo_sig.pdf - Adobe Acrobat Pro.pdf (1.29 MB)

18559_Study Protocol_Redacted_V 4.1_2019_09_27.pdf (1.84 MB)

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 topic:

Disease /health condition

Human medicinal product

Study type:

Non-interventional study

Scope of the study:

Assessment of risk minimisation measure implementation or effectiveness

Drug utilisation

Effectiveness study (incl. comparative)

Data collection methods:

Combined primary data collection and secondary use of data

Main study objective:

The primary objective of this study is to investigate weeklyprophylaxis dosing regimens used in standard clinicalpractice.

Study Design

Non-interventional study design

Other

Non-interventional study design, other

Open label, prospective, non-interventional, single arm study in patients receiving KOVALTRY as prophylaxis therapy.

Study drug and medical condition

Anatomical Therapeutic Chemical (ATC) code

(B02BD02) coagulation factor VIII

coagulation factor VIII

Medical condition to be studied

Coagulation factor VIII level decreased

Population studied

Short description of the study population

Previously treated male patients with moderate to severe (≤ 5% FVIII:C) hemophilia A, with ≥ 50 exposure days (EDs) to any FVIII product and with or without history of inhibitors who have been prescribed KOVALTRY for a medically appropriate use will be eligible to be included into this study. Indications and contraindications according to the local market authorization should carefully be considered.

Inclusion criterion/criteria

• Male patients diagnosed with moderate to severe hemophilia A (≤ 5% FVIII:C)

• Any age

• ≥ 50 exposure days (EDs) to any FVIII product

• Patients with or without history of inhibitors

• Patient with previous history of inhibitors, with at least 2 consecutive negative inhibitor tests and on standard prophylaxis therapy for at least 1 year prior to study entry

• No current evidence* of FVIII inhibitor or clinical suspicion** of FVIII inhibitor

*Evidence of FVIII inhibitor as measured by the Nijmegen-modified Bethesda assay[<0.6 Bethesda units (BU/mL)] or Bethesda assay [< 1.0 BU/mL] in 2 on consecutives samples

**Documented or clinical suspicion of shortened FVIII half-life (< 6 hrs)

• Currently on or plan to start prophylaxis therapy with KOVALTRY

• Written informed consent

Exclusion criterion/criteria

• Patients participating in an investigational program with interventions outside of routine clinical practice

• Patients with an additional diagnosis of any bleeding/coagulation disorder other than hemophilia A

• Patients on Immune Tolerance Induction (ITI) treatment at the time of enrollment

---

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)

Special population of interest

Other

Special population of interest, other

Patients with moderate to severe Hemophilia A

Estimated number of subjects

350

Study design details

Outcomes

Proportion of patients on 2x weekly prophylaxis,Proportion of patients on 3x weekly prophylaxis. Composite number of reported bleeds (total, spontaneous, joint and trauma),Number of physicians who selected the individual criteria as top 3 reason for the prophylaxis decision,Mean and median composite score for treatment satisfaction (Hemo-SAT),Incidence of adverse events (AEs) and serious adverse events (SAEs).

Data analysis plan

Statistical analyses will be explorative. All variables will be analyzed descriptively by frequency tables and/or summary statistics. Changes from baseline will be provided.

Documents

Study results

18559_EU PAS Abstract_Redacted_V1.0_2021-07-12.pdf (439.92 KB)

Study report

18559_Clinical Study Report_Redacted_V1.0_2021-07-12.pdf (2.1 MB)

Data management

Data sources

Data sources (types)

Electronic healthcare records (EHR)

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