Observational Study Evaluating Effectiveness and Safety of Real-World Treatment with Damoctocog alfa pegol in Previously Treated Patients with Hemophilia A (HEM-POWR)

First published: 29/05/2019

Last updated: 08/04/2024

Study Ongoing

Administrative details

EU PAS number

EUPAS26416

Study ID

33625

DARWIN EU® study

No

Study countries

- ☐ Austria
- ☐ Belgium

- [ ] Brazil
- [ ] Canada
- [ ] China
- [ ] Colombia
- [ ] Denmark
- [ ] Finland
- [ ] France
- [ ] Germany
- [ ] Greece
- [ ] Italy
- [ ] Japan
- [ ] Kuwait
- [ ] Luxembourg
- [ ] Mexico
- [ ] Netherlands
- [ ] Norway
- [ ] Russian Federation
- [ ] Saudi Arabia
- [ ] Slovenia
- [ ] Spain
- [ ] Sweden
- [ ] Switzerland
- [ ] Taiwan
- [ ] United Arab Emirates
- [ ] United States

Study description

The aim of the HEM-POWR study is to understand better how Damoctocog alfa pegol (Jivi) is used to treat people with Hemophilia A in day-to-day life, how well the treatment is tolerated and how satisfied patients and physicians are with

the treatment.

Study status

Ongoing

Research institutions and networks

Institutions

Bayer AG

First published: 01/02/2024

Last updated: 01/02/2024

Institution

Contact details

Study institution contact

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

Study contact

clinical-trials-contact@bayer.com

Primary lead investigator

Bayer Clinical Trials BAYER AG

Primary lead investigator

Study timelines

Date when funding contract was signed
Actual: 18/03/2019

Study start date
Planned: 15/11/2019

Actual: 21/10/2019

Date of final study report
Planned: 31/03/2026

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

BAYER AG

Study protocol

20002_HEM-POWR_OS Protocol_v 1.1_2019-03-18_Redacted.pdf (4.53 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:

Non-interventional study

Scope of the study:

Drug utilisation

Effectiveness study (incl. comparative)

Safety study (incl. comparative)

Main study objective:

To assess the effectiveness of prophylaxis with damoctocog alfa pegol in the real-world setting through the collection of total bleeding events and analysis of ABR in the different prophylaxis regimens (following approved local label), or any other regimen prescribed by the physician as part of normal clinical practice in patients with hemophilia A.

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

Medicinal product name

JIVI

Medical condition to be studied

Haemophilia A without inhibitors

Population studied

Age groups

- 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)

Estimated number of subjects

200

Study design details

Outcomes

Mean/median annualized number of reported total bleeds in patients with hemophilia A. The study will capture patterns of switching in damoctocog alfa pegol dose and dosing regimen, reasons for choice of treatment regimen, damoctocog alfa pegol consumption, adverse events, pharmacokinetics (if part of routine practice), as well as patient treatment satisfaction, work productivity and activity impairment.

Data analysis plan

Statistical analyses will be of an explorative and descriptive nature. All variables will be analyzed descriptively with appropriate statistical methods: categorical variables by frequency tables (absolute and relative frequencies) and continuous variables by sample statistics (i.e. mean, standard deviation SD, minimum, median, quartiles, and maximum). Continuous variables will be described by absolute value and as change from baseline per analysis time point, if applicable. All analyses will be performed for the total study population

(overall analysis). Separate analyses for individual participating countries or regions will be provided if required for local reasons when sufficient data is available. Annual analyses are planned to provide annual safety reports and preliminary results to support publications. The final analysis will be performed after end of the study, which is the date the analytical dataset is completely available.

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, Some data will be collected retrospective from the patients clinical records.

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