# 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

**PURI**

https://redirect.ema.europa.eu/resource/33625

**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

**Study contact**

clinical-trials-contact@bayer.com

**Primary lead investigator**

## Bayer Clinical Trials BAYER AG

# 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

## Study type list

**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

**Name of medicine**

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

# 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