

# Observational study evaluating long-term safety of real-world treatment with damoctocog alfa pegol in previously treated patients with hemophilia A (HA-SAFE)

**First published:** 18/06/2020

**Last updated:** 02/01/2025

Study

Ongoing

## Administrative details

### EU PAS number

EUPAS33520

---

### Study ID

42361

---

### DARWIN EU® study

No

---

### Study countries

- ☐ Austria
- ☐ Belgium
- ☐ Denmark

- ☐ Finland
  - ☐ Germany
  - ☐ Greece
  - ☐ Italy
  - ☐ Luxembourg
  - ☐ Netherlands
  - ☐ Norway
  - ☐ Portugal
  - ☐ Slovenia
  - ☐ Spain
  - ☐ Sweden
  - ☐ Switzerland
- 

### **Study description**

In this observational study researchers want to learn more about the safety of drug Jivi over a long period of time. Jivi (generic name: Damoctocog alfa pegolis) is an approved blood clotting Factor VIII (FVIII) medication for the treatment of hemophilia A (bleeding disorder resulting from a lack of FVIII). It is manufactured via recombinant technology and has an extended half-live, i.e. it will stay longer in the body than other FVIII products. Therefore Jivi acts longer in the body which reduces the frequency of drug injections. This study will enroll previously treated patients with hemophilia A who are receiving Jivi regularly to prevent bleeding at their treating doctors. Observation for each patient will last for at least 4 years, and medical data will be collected during patients' routine visits at their treating doctors.

---

### **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](mailto: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: 13/01/2020

---

### Study start date

Planned: 30/06/2021

Actual: 14/05/2021

---

### **Date of final study report**

Planned: 30/06/2028

## Sources of funding

- Pharmaceutical company and other private sector

## More details on funding

Bayer AG

## Study protocol

[20904\\_Study\\_Protocol\\_Redacted\\_V1.0\\_2020-01-13.pdf](#) (1.13 MB)

## Regulatory

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

Yes

---

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

EU RMP category 1 (imposed as condition of marketing authorisation)

---

### **Regulatory procedure number**

EMA/H/C/PSP/S/0070

## Methodological aspects

### Study type

### Study type list

**Study type:**

Non-interventional study

---

**Scope of the study:**

Assessment of risk minimisation measure implementation or effectiveness

**Main study objective:**

To assess the long-term safety of prophylaxis with damoctocog alfa pegol in patients with hemophilia A in the real-world setting through the collection and analysis of adverse events (AEs) of special interest including those potentially indicative of PEG accumulation), AEs, serious adverse events (SAEs), and adverse reactions (ARs).

## 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

50

# Study design details

## Outcomes

1. Number of subjects with safety events 2. Duration of safety events 3. Number of subjects with safety events leading to a change of treatment 4. Number of subjects with safety events per intensity 5. Number of subjects with safety events with outcome of death 6. Number of subjects with safety events related to inhibitor development, 1. Number of adverse reactions (ARs) that are defined within the system organ classes nervous system and psychiatric disorders 2. Number of ARs related to hepatic or renal function 3. Change from baseline in creatinine, eGFR, ALT, AST, bilirubin 4. Testing for PEG plasma levels (baseline and end of study, if collected) 5. Number of patients with abnormal findings as assessed by neurological examination

---

## Data analysis plan

Statistical analyses will be of an explorative and descriptive nature. The study is not aimed to confirm or reject predefined hypotheses, hence no formal hypothesis testing will be performed.

# Documents

## Study report

[20904 Study Report Year 3\\_for publication.pdf](#) (541.04 KB)

[20904-study-report\\_year 2\\_for publication-updated.pdf](#) (480.72 KB)

## 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

## 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