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

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Institution

Contact details

Study institution contact

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

Study contact

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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

EMEA/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

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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

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