TAK-660-403: Evaluation of Long-term Safety of ADYNOVI/ADYNOVATE (Antihaemophilic Factor [Recombinant] PEGylated, Rurioctocog Alfa Pegol) in Patients With Haemophilia A - An ADYNOVI/ADYNOVATE Post-Authorisation Safety Study (PASS) (TAK-660-403: ADYNOVI/ADYNOVATE PASS)

First published: 15/06/2020

Last updated: 14/03/2024

Study Ongoing

Administrative details

EU PAS number

EUPAS35698

Study ID

50722

DARWIN EU® study

No

Study countries

Bulgaria
Croatia
Czechia
Germany
Hungary
Italy
Korea, Republic of
Netherlands
Spain
Sweden
Taiwan

Study description

The main aim of this study is to check for long-term side effects from ADYNOVI/ADYNOVATE prophylaxis in participants with haemophilia A when used under standard clinical practice in the real-world clinical setting.

Study status

Ongoing

Research institutions and networks

Institutions

Takeda

First published: 01/02/2024

Last updated: 01/02/2024

Institution

Baxalta Innovations GmbH

Contact details

Study institution contact

Call Center Shire clinicaltransparency@shire.com

Study contact

clinicaltransparency@shire.com

Primary lead investigator

Call Center Shire

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 24/04/2019

Actual: 10/03/2020

Study start date

Planned: 20/07/2020

Actual: 09/07/2020

Date of final study report
Planned: 22/07/2030

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Baxalta Innovations GmbH, now part of Takeda

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/PSA/S/0045.1

Other study registration identification numbers and links

NCT04158934,https://clinicaltrials.gov/ct2/show/NCT04158934?term=NCT04158934&draw

Methodological aspects

Study type

Study type list

Study type:

Non-interventional study

Scope of the study:

Assessment of risk minimisation measure implementation or effectiveness

Drug utilisation

Main study objective:

The main aim of this study is to check for long-term side effects from ADYNOVI/ADYNOVATE prophylaxis in participants with haemophilia A when used under standard clinical practice in the real-world clinical setting.

Study Design

Non-interventional study design

Other

Non-interventional study design, other

Prescription event monitoring, case-series

Study drug and medical condition

Anatomical Therapeutic Chemical (ATC) code

(B02BD02) coagulation factor VIII

coagulation factor VIII

Medical condition to be studied

Haemophilia A without inhibitors

Population studied

Age groups

- Adolescents (12 to < 18 years)
- Children (2 to < 12 years)
- Infants and toddlers (28 days – 23 months)
- Preterm newborn infants (0 – 27 days)
- Term newborn infants (0 – 27 days)
- 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

Incidence of Adverse Events (AE) and Serious Adverse Events (SAE). Occurrence of AE Related to: Impaired Renal Function, Impaired Hepatic Function, Impaired Neurologic Function. Change From Baseline at Specified Time Points in: Estimated Glomerular Filtration Rate (eGFR), Alanine Aminotransferase (ALT), Bilirubin, Polyethylene Glycol (PEG) Plasma Levels. Number of Participants With Clinically Significant Abnormalities in: Vital Signs, Physical Exam, Clinical Laboratory Parameters, Neurological Exam.

Data analysis plan

All safety analyses for primary and secondary endpoints will be descriptive and, if applicable, be stratified by age group, etc. and may include arithmetic mean,

standard deviation, median, quartiles and interquartile range, minimum, maximum, percentages, frequency counts, and 95% confidence intervals of select point estimates.

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