PLEASE NOTE: *This trial has been registered retrospectively.*

Trial Description

Title

ADVATE / ADYNOVI Hemophilia A Outcome Database

Trial Acronym

AHEAD

URL of the trial

[---]*

Brief Summary in Lay Language

Non-interventional study with subjects and hemophilia A receiving the product ADVATE or ADYNOVI as routine-treatment. Documentation of those patients concerning quality of life, co-morbidity, drug utilization, effectiveness and safety of the product ADVATE and ADYNOVI will be assessed.

Brief Summary in Scientific Language

Documentation and comparison of long-term outcomes of subjects with hemophilia A receiving ADVATE or ADYNOVI in routine clinical practice in terms of quality of life, hemophilia-related co-morbidity, drug utilization, effectiveness and safety.

Do you plan to share individual participant data with other researchers?

No

Description IPD sharing plan

[---]*

Organizational Data

- DRKS-ID: **DRKS00000556**
- Date of Registration in DRKS: **2010/09/23**
- Date of Registration in Partner Registry or other Primary Registry: **[---]***
- Investigator Sponsored/Initiated Trial (IST/IIT): **no**
- Ethics Approval/Approval of the Ethics Committee: **Approved**

DRKS-ID: **DRKS00000556**
Date of Registration in DRKS: **2010/09/23**
Date of Registration in Partner Registry or other Primary Registry: **[---]***

Investigator Sponsored/Initiated Trial (IST/IIT): **no**

Ethics Approval/Approval of the Ethics Committee: **Approved**

- (leading) Ethics Committee Nr.: **260/09 , Ethik-Kommission der Medizinischen Fakultät der Rheinischen Friedrich-Wilhelms-Universität Bonn**

Secondary IDs

Health condition or Problem studied

- ICD10: **D66 - Hereditary factor VIII deficiency**
- ICD10: **[---]* - [---]***

Interventions/Observational Groups

Characteristics

- Study Type: **Non-interventional**
- Study Type Non-Interventional: **Observational study**
- Allocation: **Single arm study**
- Blinding: **[---]***
- Who is blinded: **[---]***
- Control: **Uncontrolled/Single arm**
- Purpose: **Prognosis**
- Assignment: **Single (group)**
- Phase: **N/A**
- Off-label use (Zulassungsüberschreitende Anwendung eines Arzneimittels): **[---]***

Primary Outcome

Incidence of haemophilia-affected joint-arthropathy by imaging techniques (e.g. MRI, X-ray, ultrasound) and by assessment of the treating physician using only the pain, bleeding, and physical exam parameter of the Gilbert Scale.

Secondary Outcome

Incidence of joint replacement therapies; incidence of target joint operations; Incidence of pseudo-tumor development; Pain associated with bleeding event according to VAS-Score; Quality of life using the Haemo-QoL, SF-10TM, SF-12v2TM and Haem-A-QoL questionnaires; Annualized bleed rate; Hemostatic effectiveness rating of bleeding episodes treated with ADVATE or ADYNOVI; Number of units required for bleed resolution; Number of infusions required for bleed resolution; Number of days off from school or work due to hemophilia A bleeding episodes; Incidence of inhibitors in PTPs; Incidence of inhibitors in PUPs; Incidence of inhibitors after switching to ADYNOVI; Incidence of treatment-related serious AEs; Incidence of treatment-related non-serious AEs; Compliance with the dosing prescribed and its relationship with effectiveness in prophylaxis regimen; Modalities of switching from a standard FVIII product to ADYNOVI (prophylaxis regimen)
- Difference in number of weekly prophylactic infusions between previous regimen and ADYNOVI
- Difference in number of weekly doses between previous regimen and ADYNOVI; Status of joint health using the Hemophilia Joint Health Score (HJHS) in patients on ADYNOVI

Countries of recruitment

- DE **Germany**

Locations of Recruitment

Recruitment

- Planned/Actual: **Actual**
- (Anticipated or Actual) Date of First Enrollment: **2010/06/07**
- Target Sample Size: **500**
- Monocenter/Multicenter trial: **Multicenter trial**
- National/International: **National**

Inclusion Criteria

- Gender: **Both, male and female**
- Minimum Age: **no minimum age**

Gender: **Both, male and female**

Minimum Age: **no minimum age**

- Maximum Age: **no maximum age**

Additional Inclusion Criteria

Subject has moderate or severe hemophilia A (baseline factor VIII < 5%) and is being treated with ADVATE or ADYNOVI on any treatment regimen recommended by his/her treating physician. Subject, parent(s) or legally authorized representative has provided written informed consent. For ADYNOVI: Subject aged ≥ 12 years

Exclusion criteria

Subject has known hypersensitivity to the active substance or to any of the excipients. Subject has a known allergic reaction to mouse or hamster proteins.

Addresses

- **Primary Sponsor**

Takeda Pharma Vertrieb GmbH & Co. KG
Jägerstr. 27
10117 Berlin
Germany

Telephone: **+49-30 20658 220**
Fax: **+49-30 20658 22100**
E-mail: **[---]***
URL: **[---]***

- **Contact for Scientific Queries**

Takeda Pharma Vertrieb GmbH & Co. KG
Mr. Dr. med. Stephan Regensburger
Friedrichstraße 149
10117 Berlin
Germany

Telephone: **+49-30 20658 2238**
Fax: **+49-30 20658 2100**
E-mail: **stephan.regensburger at takeda.com**
URL: **www.takeda.de**

- **Contact for Public Queries**

Contact for Public Queries

Takeda Pharma Vertrieb GmbH & Co. KG
Mr. Dr. med. Stephan Regensburger
Friedrichstraße 149
10117 Berlin
Germany

Telephone: **+49-30 20658 2238**
Fax: **+49-30 20658 2100**
E-mail: **stephan.regensburger at takeda.com**
URL: **www.takeda.de**

Sources of Monetary or Material Support

- **Commercial (pharmaceutical industry, medical engineering industry, etc.)**

Takeda Pharma Vertrieb GmbH & Co. KG
Jägerstr. 27
10117 Berlin
Germany

Telephone: **+49-30 20658 20**
Fax: **+49-30 20658 2110**
E-mail: **[---]***
URL: **[---]***

Status

- Recruitment Status: **Recruiting ongoing**
- Study Closing (LPLV): **[---]***

Trial Publications, Results and other documents

** This entry means the parameter is not applicable or has not been set.*
**** This entry means that data is not displayed due to insufficient data privacy clearing.*