PLEASE NOTE: This trial has been registered retrospectively.

Trial Description

Title

AHEAD: ADVATE (Octocog alfa) 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 as routine-treatment. Documentation of those patients concerning quality of life, co-morbidity, drug utilization, effectiveness and safety of the product ADVATE will be assessed.

Brief Summary in Scientific Language

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

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
- (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; Number of units required for bleed resolution; Number of infusions required for bleed resolution; Number of days lost from school or work due to hemophilia A bleeding episodes; Incidence of inhibitors in PTPs with FVIII < 5%; Incidence of inhibitors in PUPs with FVIII < 5%; Incidence of treatment-related serious AEs; Incidence of treatment-related non-serious AEs

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**
- 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 on any treatment regimen recommended by his/her treating physician. Subject, parent(s) or legally authorized representative has provided written informed consent.

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**
  
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Primary Sponsor

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Sources of Monetary or Material Support

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

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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.