**Study of Haemodialysis Patients Switching From Aranesp to Biosimilar (SHADE)**

**Purpose**

The study will obtain data to show insight into clinical outcomes of patients switching from Darbepoetin Alfa to an epoetin alfa biosimilar.

**Condition**

Anaemia

**Study Type:** Observational

**Study Design:** Time Perspective: Retrospective

**Official Title:** Retrospective Study of Stable Haemodialysis Patients Switched From Darbepoetin Alfa to Epoetin Alfa Biosimilar

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**Primary Outcome Measures:**

- Haemoglobin Concentration [ Time Frame: Duration of observation period -52 weeks ] [ Designated as safety issue: No ]
  
  Mean haemoglobin concentration over time

**Secondary Outcome Measures:**

- ESA Doses [ Time Frame: Duration of observation period -52 weeks ] [ Designated as safety issue: No ]
  
  Doses of ESA over time.

- Dose ratio [ Time Frame: Start post-switch (weeks 1-4) and pre-switch (weeks 4--1) ] [ Designated as safety issue: No ]
  
  Dose ratio between the start of the post-switch observation period and pre-switch

- Dose ratio [ Time Frame: Between end of post-switch (weeks 23-26) and pre-switch (weeks 4--1) ] [ Designated as safety issue: No ]
  
  Dose ratio between the end of the post-switch observation period and pre-switch
Haemoglobin excursions [ Time Frame: Duration of observation period -52 weeks ] [ Designated as safety issue: No ]
Haemoglobin excursions (<10/dL and >12g/dL)

Haemoglobin within range [ Time Frame: Duration of observation period -52 weeks ] [ Designated as safety issue: No ]
Haemoglobin in the range 10-12g/dL over time

TSAT, ferritin and albumin values [ Time Frame: Duration of observation period -52 weeks ] [ Designated as safety issue: No ]
TSAT, ferritin and albumin over time

Iron Use [ Time Frame: Duration of observation period -52 weeks ] [ Designated as safety issue: No ]
Iron use (dose/route) over time

Red cell transfusions (including number of units transfused) [ Time Frame: Duration of observation period -52 weeks ]
[ Designated as safety issue: No ]
Red cell transfusions (including number of units transfused)

Hospitalisations (including primary cause) [ Time Frame: Duration of observation period -52 weeks ] [ Designated as safety issue: No ]
Hospitalisations (including primary cause)

Other Outcome Measures:
- Number of Subjects with PRCA testing and incidence of neutralizing anti-erythropoietin antibodies [ Time Frame: Duration of 52-week observation period ] [ Designated as safety issue: Yes ]
  Pure Red Cell Aplasia (PRCA) test and results

Estimated Enrollment: 320
Study Start Date: June 2014
Estimated Study Completion Date: May 2015
Estimated Primary Completion Date: March 2015 (Final data collection date for primary outcome measure)

Groups/Cohorts

Cohort 1
Patients with CKD

Detailed Description:
Biosimilars were approved in 2007 by the EMA in EU and in 2010 by the TGA in Australia. This study will look at the retrospective data of patients that have switched from Darbepoetin Alfa to an approved epoetin alfa biosimilar. Data will be collected for the 26 week period prior to switch and a 26 week period post switch to a biosimilar. Data to be collected includes haemoglobin measurements, dose requirements, iron use, any transfusions, hospitalisations and other lab values including TSAT, Ferritin and albumin. Data from the study will be published.

Eligibility

Ages Eligible for Study: 18 Years and older
Genders Eligible for Study: Both
Accepts Healthy Volunteers: No
Sampling Method: Probability Sample

Study Population
The study population comprises prevalent haemodialysis (HD) patients treated at EU and Australian dialysis clinics after September 2008. Eligible patients will have received treatment with darbepoetin alfa for at least 26 weeks prior to being converted to an EMA/TGA-approved epoetin alfa biosimilar. At each participating study site, all potentially eligible patients are to be considered for enrolment.

Criteria
Inclusion Criteria
- Patients ≥18 years of age
- Patients with CKD on haemodialysis and fulfilling the following:
  - Received HD for at least 26 weeks prior to switching from treatment with darbepoetin alfa to treatment with an EMA/TGA-approved epoetin
Received darbepoetin alfa treatment i.v. for at least 26 weeks immediately prior to switching to an EMA/TGA-approved epoetin alfa biosimilar (breaks due to treatment being intentionally withheld are permitted)

- Switched from darbepoetin alfa treatment to an EMA/TGA-approved epoetin alfa biosimilar at least 26 weeks prior to enrolment
- Received at least one dose of an EMA/TGA-approved epoetin alfa biosimilar after switching from darbepoetin alfa treatment

- Mean monthly Hb 10-12g/dL in the 12 weeks prior to switch
- Stable darbepoetin alfa dose (i.e. no more than one increment or decrement of PFS) in the 12 weeks prior to switch
- Patient or patient's legally acceptable representative has provided informed consent, if applicable according to local requirements

Exclusion Criteria:
- Treatment with an ESA other than darbepoetin alfa during the 12 weeks prior to switch to biosimilar
- More than 14 days' cumulative treatment with short-acting ESA during weeks 26-13 prior to switch to biosimilar
- Subject received chemotherapy or major surgery during the 26 weeks prior to switch to biosimilar
- Subject was enrolled in an interventional device or drug study at any time during the 52-week data observation period or within 30 days prior to commencement of the data observation period.

Contacts and Locations

Choosing to participate in a study is an important personal decision. Talk with your doctor and family members or friends about deciding to join a study. To learn more about this study, you or your doctor may contact the study research staff using the Contacts provided below. For general information, see Learn About Clinical Studies.

Please refer to this study by its ClinicalTrials.gov identifier: NCT02191150

Contacts
Contact: Amgen Call Center 866-572-6436

Locations
Greece
Research Site Recruiting
Egaleo, Greece, 12242
Research Site Recruiting
Kallithea, Athens, Greece, 17676

Italy
Research Site Recruiting
Pisa, Italy, 56124

Poland
Research Site Recruiting
Chojnice, Poland, 89-600

Sponsors and Collaborators
Amgen

Investigators
Study Director: MD Amgen

More Information

Additional Information:

AmgenTrials clinical trials website

No publications provided

Responsible Party: Amgen
ClinicalTrials.gov identifier: NCT02191150
Other Study ID Numbers: 20130300
Study First Received: July 7, 2014
| Health Authority | Greece: Each site's local Ethics Committee  
|                 | Italy: Local Ethics Committees  
|                 | Italy: RSO (Register of Observational Studies)  
|                 | Italy: AIFA  
|                 | Bulgaria: Bulgarian Drug Agency  
|                 | Bulgaria: Ethics Committee for Multicenter Trials (ECMT)  
|                 | Spain: Agencia Española de Medicamentos y Productos Sanitarios  
|                 | Poland: Not applicable  
|                 | Australia: Princess Alexander Hospital Ethics Committee  

Keywords provided by Amgen:
Anaemia, Chronic Kidney Disease, Switching, Aranesp, Darbepoetin Alfa, Epoetin Alfa Biosimilars, Haemodialysis.

Additional relevant MeSH terms:
Darbepoetin alfa
Hematinics
Hematologic Agents
Therapeutic Uses
Pharmacologic Actions

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