Use of Erythropoiesis Stimulating Agents (ESAs) in Patients Receiving Myelosuppressive Chemotherapy in Europe and the UK (20190404)

First published: 22/11/2022

Last updated: 15/10/2024

Study Ongoing

Administrative details

PURI

https://redirect.ema.europa.eu/resource/50771

EU PAS number

EUPAS49757

Study ID

50771

DARWIN EU® study

No

Study countries

- [ ] Belgium
- [ ] France
- [ ] Germany
- [ ] Italy
- [ ] Spain
- [ ] United Kingdom

Study status

Ongoing

Research institutions and networks

Institutions

Amgen

- [ ] United States

First published: 01/02/2024

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Institution

Contact details

Study institution contact

Global Development Leader Amgen Inc.

Study contact

medinfo@amgen.com

Primary lead investigator

Global Development Leader Amgen Inc.

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 06/01/2020

Study start date

Planned: 20/01/2023

Actual: 27/01/2023

Data analysis start date

Planned: 30/09/2024

Actual: 30/09/2024

Date of final study report

Planned: 30/09/2025

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Amgen

Study protocol

Protocol-Published Amendment darbepoetin alfa 20190404 4 redacted.pdf (742.8 KB)

Protocol-Published Amendment darbepoetin alfa 20190404 6.pdf(791.03 KB)

Regulatory

Was the study required by a regulatory body?

Yes

Is the study required by a Risk Management Plan (RMP)?

EU RMP category 3 (required)

Methodological aspects

Study type

Study type list

Study topic:

Human medicinal product

Study type:

Non-interventional study

Scope of the study:

Drug utilisation

Effectiveness study (incl. comparative)

Other

If ‘other’, further details on the scope of the study

Observe disease-related baseline characteristics at initiation of treatment

Main study objective:

The primary objective of this study is to describe the baseline hemoglobin (Hb) levels at initiation of treatment with erythropoiesis stimulating agent (ESA) in participants receiving myelosuppressive chemotherapy.

Study Design

Non-interventional study design

Other

Non-interventional study design, other

Retrospective multi-centre observational study

Study drug and medical condition

Name of medicine

ARANESP

Study drug International non-proprietary name (INN) or common name

DARBEPOETIN ALFA

Anatomical Therapeutic Chemical (ATC) code

(B03XA02) darbepoetin alfa

darbepoetin alfa

Medical condition to be studied

Anaemia

Population studied

Age groups

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

1625

Study design details

Outcomes

Hb level in g/dL at initiation of ESA, further categorised in 2 alternative ways, as per product label and clinical trial criteria.

• Hb ≤10 g/dL

• Hb ≤11 g/dL, Demographic characteristics, average prescription length of ESA, number of participants with ESA prescribed at Weeks 3, 4, 6, 9, prescribed dose, frequency and dose modifications, Hb level during ESA treatment, change in Hb level during ESA treatment.

Data analysis plan

For the primary objective, the number and proportion (%) of patients receiving myelosuppressive chemotherapy with a baseline Hb level of

• 10 g/dL (as per SmPC criteria), and

• 11 g/dL (as per 20070782 clinical trial criteria) prior to or at initiation of ESA treatment will be summarized with descriptive statistics.
Point estimates for the proportions, mean, and median will be presented with 95% confidence intervals (CI) for proportion and mean estimates and 1st and 3rd quartiles for median estimates. Patient demographics, clinical characteristics, type of ESA will be summarized with descriptive statistics overall and by ESA type, and country, where appropriate. The number of weeks of treatment with an ESA and starting dose, dose frequency and any dose modifications will also be summarized. All analyses will be stratified by ESA type, type of malignancy and country.

Data management

Data sources

Data sources (types)

Drug dispensing/prescription data

Other

Data sources (types), other

Retrospective patient based data collection, patient medical records and charts (both electronic and/or paper based) as well as pathology and pharmacy databases.

Use of a Common Data Model (CDM)

CDM mapping

No

Data quality specifications

Check conformance

Yes

Check completeness

Yes

Check stability

Yes

Check logical consistency

Yes

Data characterisation

Data characterisation conducted

No