Use of Erythropoiesis Stimulating Agents (ESA) in Patients With Non-myeloid Malignancies Receiving Myelosuppressive Chemotherapy 2014 – 2021 (20170210)

First published: 25/05/2018

Last updated: 22/01/2025

Study Finalised

Administrative details

EU PAS number

EUPAS24079

Study ID

28521

DARWIN EU® study

No

Study countries

☐ United States

Study description

The study utilizes data from the Truven MarketScan claims database and the US-based Oncology Services Comprehensive Electronic Records (OSCER) database. Both databases were used to evaluate the use of ESAs after the initiation of myelosuppressive chemotherapy among patients diagnosed with non-myeloid malignancy. Patients were further categorized into the following specific tumor types: breast cancer, breast cancer receiving adjuvant therapy, metastatic breast cancer, CRC, lymphoma, lung cancer, and NSCLC. The study aims are: 1) To estimate the proportion of patients with non myeloid malignancies receiving an ESA over a 180-day follow-up period after initiation of myelosuppressive chemotherapy by calendar year, overall and stratified by specific tumor types (described above); and 2) To describe the hemoglobin (Hb) levels and estimate the proportion of patients with Hb values greater than 10 g/dL immediately preceding ESA treatment initiation in patients with non-myeloid malignancies after initiation of myelosuppressive chemotherapy by calendar year, overall and stratified by specific tumor types described above.

Study status

Finalised

Research institutions and networks

Institutions

Amgen

United States

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Last updated: 21/02/2024

Institution

Contact details

Study institution contact

Global Development Leader Amgen Inc.

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Study contact

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Primary lead investigator

Global Development Leader Amgen Inc.

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 02/01/2017

Actual: 02/01/2017

Study start date

Planned: 19/05/2017

Actual: 19/05/2017

Data analysis start date

Planned: 01/09/2023

Actual: 22/09/2023

Date of interim report, if expected
Planned: 31/03/2018

Date of final study report
Planned: 31/01/2024

Actual: 31/01/2024

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Amgen

Study protocol

01.02.06 Public Redacted Protocol Ver 1.0 English.pdf(854.75 KB)

Regulatory

Was the study required by a regulatory body?

Yes

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

Not applicable

Methodological aspects

Study type

Study type list

Study type:

Non-interventional study

Scope of the study:

Other

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

To assess the utilization of Aranesp or Epogen/Procrit for the treatment of anemia in patients with non-myeloid malignancies where anemia is due to the effect of concomitant myelosuppressive chemotherapy

Main study objective:

To assess the utilization of Aranesp or Epogen/Procrit for the treatment of anemia in patients with non-myeloid malignancies where anemia is due to the effect of concomitant myelosuppressive chemotherapy stratified by calendar year and selected tumor types

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

Name of medicine

ARANESP

Name of medicine, other

Epogen/Procrit

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

Microcytic 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

1100000

Study design details

Outcomes

Estimate the proportion of patients with non-myeloid malignancies receiving an ESA over a 180 day follow-up period after initiation of myelosuppressive chemotherapy by calendar year, overall and stratified by specific tumor types including patients with breast cancer, adjuvant breast cancer, metastatic breast

cancer, CRC, lung cancer, NSCLC, and lymphoma. Describe the demographic and clinical characteristics of patients with non-myeloid malignancies after initiation of myelosuppressive chemotherapy by calendar year, overall and stratified by specific tumor types including patients with breast cancer, adjuvant breast cancer, metastatic breast cancer, CRC, lung cancer, NSCLC, and lymphoma.

Data analysis plan

The incidence proportion (%) and 95% CIs for ESA use during the 180-day follow-up period and the proportion of patients with Hb values > 10 g/dL at the time of ESA initiation were estimated for the population overall and by specific tumor type. The 95% CI surrounding the incidence estimate was based on the binomial distribution. The incidence proportion for ESA use was defined as the number of patients who received at least 1 ESA administration during follow-up divided by the number of patients at risk in the cohort at the beginning of follow-up. The incidence proportion for patients with Hb values > 10 g/dL was defined as the number of patients with Hb values > 10 g/dL divided by the number of patients with observed Hb values at the time ESA initiation. All analyses were conducted by calendar year cohort.

Documents

Study report

ORSR Abstract 20170210.pdf(56.86 KB)

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 source(s), other

- Truven MarketScan claims database
- OSCER database

Data sources (types)

Administrative healthcare records (e.g., claims)

Drug dispensing/prescription data

Electronic healthcare records (EHR)

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