Association Between Granulocyte Colony Stimulating Factor (G-CSF) use and Myelodysplastic Syndrome (MDS) or Acute Myeloid Leukemia (AML) Among Elderly Patients With Breast (Stage I-III), lung (Stage I-III) or Prostate (Stage I-IV) Cancer

First published: 24/07/2017

Last updated: 22/02/2024

Study Finalised

Administrative details

PURI

https://redirect.ema.europa.eu/resource/39702

EU PAS number

EUPAS19718

Study ID

39702

DARWIN EU® study

No

Study countries

United States

Study description

To describe the treated breast, lung, and prostate cancer population aged 66 years and over, Estimate the risk of MDS/AML for patients, and compare the risk of MDS/AML by treatment modality, chemotherapy regimen and G-CSF prophylaxis

Study status

Finalised

Research institutions and networks

Institutions

Amgen

United States

First published: 01/02/2024

Last updated: 21/02/2024

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: 31/07/2017

Actual: 31/07/2017

Study start date

Planned: 31/07/2018

Actual: 31/07/2018

Data analysis start date

Planned: 30/04/2019

Actual: 26/04/2019

Date of final study report

Planned: 31/03/2020

Actual: 30/11/2020

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Amgen Inc

Study protocol

20160176_01.02.06 Public Redacted Protocol Ver 1.0 2018-08-22 English.pdf
(1.05 MB)

20160176_01.02.06 Public Redacted Protocol Ver 1.0 2019-01-10 English.pdf
(792.99 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

Disease /health condition

Study type:

Non-interventional study

Scope of the study:

Assessment of risk minimisation measure implementation or effectiveness

Data collection methods:

Secondary use of data

Main study objective:

Among breast, lung, and prostate cancer patients, assess risk of developing second primary myelodysplastic syndromes or acute myeloid leukemia by treatment modality

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

Anatomical Therapeutic Chemical (ATC) code

(L03AA) Colony stimulating factors

Colony stimulating factors

Medical condition to be studied

Breast cancer

Myelodysplastic syndrome

Acute myeloid leukaemia

Population studied

Short description of the study population

Any patients diagnosed with stage I-III breast, lung, prostate cancer between January 1, 2001 and December 31, 2014 and who satisfy the inclusion and exclusion
criteria will be included in the study.

Inclusion Criteria

Patients must satisfy the following criteria:

− Chemotherapy following first diagnosis of breast (stage I-III), lung (stage I-III) or prostate (stage I-IV) cancer

− Index date (Sixtieth day without chemotherapy following last dose of first chemotherapy course) between Jan 1, 2001 and Dec 31, 2014

− Alive and at least 66 years of age at index date

− Continuous enrollment in both Part A and Part B Medicare for at least 12 months prior to the index date

Exclusion Criteria

Patients must not have any of the following criteria:

− Breast, lung, or prostate cancer is not their first primary cancer diagnosis

− Breast, lung, or prostate breast cancer diagnosis identified only at autopsy or on their death certificate

− Men with breast cancer diagnosis

− Unknown stage at first cancer diagnosis

− End-stage renal disease (ESRD) any time prior to the index date.

− Enrolled in Health maintenance organization (HMO) any time during the study period

− Diagnosed with MDS/AML or any other second primary cancer diagnosis any time prior to the index date.

Age groups

Adults (65 to < 75 years)

Adults (75 to < 85 years)

Adults (85 years and over)

Special population of interest

Other

Special population of interest, other

Breast cancer, Myelodysplastic syndrome, Acute myeloid leukaemia patients

---

Estimated number of subjects

56000

Study design details

Outcomes

myelodysplastic syndromes or acute myeloid leukemia, Competing risk events: death, second primary malignancy (not MDS or AML), censoring

---

Data analysis plan

Time at risk for developing MDS/AML begins 60 days after end of last treatment. AML ascertained from SEER registry primary malignancy field. MDS from 2001-2009 ascertained by presence of 2 diagnosis codes in claims. 2010+ MDS ascertained by SEER registry primary malignancy field. Cox hazard models to

estimate risk of developing MDS/AML.

Documents

Study results

01.09.01 Clinical Study Report 2020-03-19 20160176 Original_Redacted.pdf

(439.95 KB)

Data management

Data sources

Data sources (types)

Administrative healthcare records (e.g., claims)

Disease registry

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