Risk factors For Bone Pain among Neulasta® Users (20120320)

First published: 11/02/2014

Last updated: 17/07/2015

Study Finalised

Administrative details

EU PAS number

EUPAS5644

Study ID

10330

DARWIN EU® study

No

Study countries

- [ ] Australia
- [ ] Austria
- [ ] Belgium
- [ ] Canada
- [ ] France
- [ ] Germany

- [ ] Italy
- [ ] Luxembourg
- [ ] Mexico
- [ ] Netherlands
- [ ] Poland
- [ ] Portugal
- [ ] Russian Federation
- [ ] Spain
- [ ] Sweden
- [ ] United Kingdom
- [ ] United States

Study description

The purpose of this study is to identify risk factors for developing bone pain among Neulasta® users. Patient data from 23 pegfilgrastim clinical trials were analyzed. Multivariable logistic regression models were used to evaluate risk factors associated with moderate to severe (grade ≥ 2) bone pain and any grade bone pain in the first chemotherapy cycle and across cycles 1–6.

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

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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

Actual: 13/08/2012

Study start date

Actual: 15/08/2012

Data analysis start date

Actual: 12/02/2013

Date of final study report
Planned: 01/05/2014

Actual: 13/07/2015

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Amgen

Study protocol

Neulasta_20120320_Protocol_11Feb14.pdf(138.19 KB)

Regulatory

Was the study required by a regulatory body?

No

Methodological aspects

Study type

Study type list

Study topic:

Human medicinal product

Disease /health condition

Study type:

Non-interventional study

Scope of the study:

Disease epidemiology

Data collection methods:

Secondary use of data

Main study objective:

The purpose of this study is to identify risk factors for developing bone pain among Neulasta® users. Patient data from 23 pegfilgrastim clinical trials were analyzed. Multivariable logistic regression models were used to evaluate risk factors associated with moderate to severe (grade ≥ 2) bone pain and any grade bone pain in the first chemotherapy cycle and across cycles 1–6.

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

Name of medicine

NEULASTA

Medical condition to be studied

Bone pain

Population studied

Short description of the study population

Adult patients with non-myeloid malignancies who received myelosuppresive chemotherapy regimens and were at risk of developing Febrile Neutropenia

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)

Special population of interest

Other

Special population of interest, other

Patients with non-myeloid malignancy

Estimated number of subjects

1974

Study design details

Outcomes

The primary endpoint is the occurrence of moderate to severe bone pain (grade 2+) in cycle 1 of the study treatment chemotherapy, captured as part of Adverse Event reporting. Moderate to severe bone pain across cycles 1-6, and bone pain of any grade in cycle 1 and bone pain of any grade across cycles 1-6.

Data analysis plan

Multivariable logistic regression models were used to identify risk factors associated with the occurrence of bone patin of grade ≥2 or any grade in cycle 1 and across cycles 1-6. Data collected in the trials and included in the regression model include: baseline patient characteristics (gender, region, race, age, body surface area, and baseline absolute neutrophil count), disease characteristics (primary tumor type, tumor stage), treatment characteristics (chemotherapy, radiotherapy, taxane vs no taxane treatment, and dose of pegfilgrastim), and medical history (osteoporosis/osteopenia, hypercholesteremia, anemia, neutropenia, osteomyelitis/osteonecrosis, arthritis, peripheral neuropathy, chronic fatigue syndrome, gout, bone fracture, and bone pain).

Documents

Study results

Final study report for protocol 20120320_FV_PKM _13JUL2015.pdf(1.8 MB)

Data management

Data sources

Data sources (types)

Other

Data sources (types), other

Patient data from 23 pegfilgrastim clinical trials sponsored by Amgen

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