An Observational Study to Assess the Effectiveness of the Neulasta® Patient Alert Card and to Measure Medication Errors Related to the Use of the Neulasta® On-Body Injector (20170701)

First published: 09/04/2019

Last updated: 05/06/2024

Study Finalised

Administrative details

EU PAS number

EUPAS28762

Study ID

50359

DARWIN EU® study

No

Study countries

- ☐ Germany
- ☐ Netherlands

Slovakia

United Kingdom

Study status

Finalised

Research institutions and networks

Institutions

Amgen

United States

First published: 01/02/2024

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Institution

Multiple centres: 20 centres are involved in the study

Contact details

Study institution contact

Global Development Leader Amgen Inc.
medinfo@amgen.com

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: 15/03/2019

Actual: 15/03/2019

Study start date

Planned: 31/03/2020

Actual: 31/03/2020

Data analysis start date

Planned: 31/03/2022

Actual: 13/01/2022

Date of final study report

Planned: 30/04/2022

Actual: 09/08/2022

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Amgen

Study protocol

csr-20170701-protocol_public-redacted-approved-version.pdf(1.72 MB)

Regulatory

Was the study required by a regulatory body?

No

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

EU RMP category 3 (required)

Methodological aspects

Study type

Study type list

Study topic:

Disease /health condition

Human medicinal product

Study type:

Non-interventional study

Scope of the study:

Effectiveness study (incl. comparative)

Data collection methods:

Primary data collection

Main study objective:

The primary objective of the study is to assess respondent awareness of key safety messages and behavioural intent to carry out recommended actions as described in the PAC.

Study Design

Non-interventional study design

Cross-sectional

Other

Non-interventional study design, other

Observational study

Study drug and medical condition

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

PEGFILGRASTIM

Medical condition to be studied

Neutropenia

Febrile neutropenia

Population studied

Short description of the study population

Patients aged 18 years or more who were prescribed the on-body injector (OBI for Neulasta delivery for their current chemotherapy cycle in 3 EU countries: Belgium, Germany, and Slovakia.

Inclusion criteria:

− Respondent (ie, patients or caregivers primarily responsible for monitoring the OBI) who agrees to be contacted for the questionnaire.

− Respondent aged 18 or more years.

− Respondent with no cognitive impairment.

− Respondent who can read and understand the language in which the study is being conducted and in which the PAC is provided.

− Patient has been prescribed the OBI for Neulasta delivery for their current chemotherapy cycle.

− Patient and respondent provide their written informed consent to participate in the study.

Exclusion criteria:

− Respondent personally works, or works on a consultancy basis, for any pharmaceutical company or advertising/research agency.

− Patient has participated or is participating in a clinical trial of Neulasta administered via OBI.

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

80

Study design details

Outcomes

Awareness of key safety messages and behavioural intent to carry out recommended actions as described in the PAC: will be evaluated using a set of multiple choice questions included in the questionnaire. A composite score for each individual will be calculated based on the proportion of all awareness and behavioural intent questions with correct responses. • To determine if the respondent received the PAC. • To estimate the proportion of OBI administrations associated with medication error.

Data analysis plan

All analyses will be descriptive. Continuous variables will be summarised by mean, median, standard deviation, Q1, Q3, minimum, maximum, 95% confidence intervals and number of valid and missing values for outcome variables. Categorical variables will be summarised by number and percentage of responses per category and 95% confidence intervals for outcome variables. The number of valid and missing values will be reported for each variable. Missing values will not be included in the denominator to calculate the percentage of responses per response category.

Documents

Study results

20170701 01.47.01.03 Public Results Redacted ORSR_Redacted.pdf(92.42 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 sources (types)

Other

Data sources (types), other

Cross-sectional survey

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