Modalities of G-CSF Zarzio® use in clinical practice in patients receiving cytotoxic chemotherapy regimens in which the rest period does not exceed 14 days for breast, lung, gastrointestinal cancers and lymphoma. (TOPAZE)

First published: 02/11/2015

Last updated: 28/04/2025

Study Ongoing

Administrative details

EU PAS number

EUPAS11465

Study ID

18897

DARWIN EU® study

No

Study countries

France

Study description

This TOPAZE study is a French national, multicenter, prospective and descriptive, non-interventional study, in patients initiating Zarzio® treatment and receiving a cytotoxic chemotherapy in which the rest period does not exceed 14 days. Use of G-CSF (Granulocyte Colony Stimulating Factors) to prevent chemotherapy-induced febrile neutropenia (FN) was defined in the EORTC’s guidelines in 2006, updated in 2010: primary prophylaxis by G-CSF is recommended in patients receiving a chemotherapy regimen with high risk of FN (≥20%) or an intermediate risk (10–20%) associated with other risk factors, but also to maintain dose-dense or dose-intense chemotherapy in order to preserve survival benefits. However, there are no clear recommendations concerning chemotherapy regimens in which the rest period do not exceed 14 days. Today, a significant number of chemotherapy regimens are weekly or every two weeks administered, or three or four weeks administered, but with a rest period of less than 14 days.Besides, these chemotherapies are often associated with targeted therapies, and there are no specific recommendations in these situations.The main objective of this study is to describe Zarzio® modalities of clinical daily use in patients receiving chemotherapy regimens with a rest period no exceeding 14 days (≤ 14 days).Data will be collected from information available as routine practice: Demographic data, Description of tumoral disease, Medical history and comorbidity factors, Clinical evaluation, Concomitant medications, Patient laboratory data, Zarzio® treatment, Chemotherapy treatment, Adverse events.All data collected will be anonymized thus protecting patient's confidentiality.No interventional procedures or change to routine medical practice are required for

Study status

Ongoing

Research institutions and networks

Institutions

Sandoz

First published: 01/02/2024

Last updated: 01/02/2024

Institution

Contact details

Study institution contact

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Study contact

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Primary lead investigator

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Primary lead investigator

Study timelines

Date when funding contract was signed

Actual: 05/01/2015

Study start date

Planned: 16/11/2015

Actual: 25/11/2015

Date of final study report
Planned: 29/03/2019

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

SANDOZ

Regulatory

Was the study required by a regulatory body?

No

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:

Drug utilisation

Main study objective:

Describe modalities of Zarzio® use in routine clinical practice, for the prevention of febrile neutropenia, in patients receiving cytotoxic chemotherapy in which the rest period* does not exceed 14 days, for the treatment of a breast, lung, gastrointestinal cancer, or a lymphoma.*Rest period= duration between two cytotoxic administrations, with the same cycle or between 2 different cycles.

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

Medical condition to be studied

Febrile neutropenia

Breast cancer

Lung neoplasm malignant

Gastrointestinal carcinoma

Lymphoma

Neutropenia

Chemotherapy

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

1431

Study design details

Outcomes

Description of modalities of Zarzio® use in patients receiving a cytotoxic chemotherapy in which the rest period does not exceed 14 days:Date of Zarzio® onset,Zarzio® Treatment duration/Frequency/daily dose administered/Type of administration,Date and reason of Zarzio® discontinuation (if applicable),Comparison of Zarzio® administration versus initial prescription,Ongoing chemotherapy. Proportion of patients with a chemotherapy dose-intensity maintained with the use of Zarzio®, Characteristics of patients treated by Zarzio®, Factors related to a primary prophylaxis versus secondary prophylaxis, Characteristics of the patients' subgroup aged of 65 years and above receiving Zarzio®.

Data analysis plan

The sample size calculation relies on the alpha risk and on the precision level desired for presenting observed frequencies.The primary objective is to describe the conditions of Zarzio® use in patients receiving a chemotherapy in which the rest period does not exceed 14 days.In order to have a sufficient

precision for each tumor type, the number of patients has been calculated independently for each type of tumor. The recruitment will be competitive.For each solid tumor (breast, lung, gastrointestinal cancer), a 5% precision is expected. For lymphoma, a 8% precision is expected.Descriptive analysis:Qualitative variables: effective and frequency, CI 95%,Quantitative variables: mean, standard deviation, CI 95%, median, quartiles and extreme valuesUnivarious analysis:Qualitative variables: association measured by Pearson’s chi-squared test,Quantitative variables: Student test if normal distribution /non parametric test if application conditions are not met.

Data management

Data sources

Data sources (types)

Other

Data sources (types), other

Prospective patient-based data collection

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