Real life effect of an epoietin alpha biosimilar Retacrit® on response to chemotherapy-induced anemia and fatigue at 16 weeks in elderly patients (ELDER)

First published: 03/04/2018

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Study Planned

Administrative details

EU PAS number

EUPAS23428

Study ID

23429

DARWIN EU® study

No

Study countries

France

Study description

Non-interventional longitudinal, prospective, multicenter, cohort study conducted among a representative sample of public and/or private hospital-based oncologists and hematologists practicing in France. Data will be collected by the physician during three visits, from the patient’s medical record, questioning and clinical examination performed during these visits :Baseline visit – V1 initiation of Retacrit®.Follow-up visit – V2: 8 weeks after inclusion.Follow-up visit – V3: maximum 16 weeks after inclusion or 4 weeks after the last recorded dose of ESA or current chemotherapy regimen. Data regarding the patient’s fatigue will be collected directly by the patients using the FACIT-Fatigue scale filled in at each visit.The primary objective of this study is to assess, in real-life settings, the effect of an ESA biosimilar (Retacrit®) on chemotherapy induced anemia response rate(a) and fatigue (FACIT-Fatigue)(b) at 16 weeks in elderly patients (aged 70 years and over) and to confirm the possible relationship between these two criteria.The secondary objectives:Determine the impact of an ESA biosimilar (Retacrit®) on performance status at 16 weeks.Assess the modalities of use of an ESA biosimilar (Retacrit®) and its safety on this specific population.Physician selection: 200 oncologists and/or hematologist.Patient selection: physicians will be allowed to include 10 patients, with the potential to enroll more subjects upon sponsor approval, until a cohort of around 1.800 patients has been obtained.

Study status

Planned

Research institutions and networks

Institutions

Pfizer

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Institution

Networks

NIHR Medicines for Children Research Network

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Network

Contact details

Study institution contact

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Study contact

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Primary lead investigator

Nadir MAMMAR

Primary lead investigator

Study timelines

Date when funding contract was signed
Planned: 12/06/2015

Study start date
Planned: 01/10/2015

Date of final study report
Planned: 01/12/2018

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

PFIZER

Study protocol

C3-Protocole_2015 09 07_EN.pdf (4.59 MB)

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:

Non-interventional study

Scope of the study:

Assessment of risk minimisation measure implementation or effectiveness

Drug utilisation

Effectiveness study (incl. comparative)

Main study objective:

To assess, in real-life settings, the effect of an ESA biosimilar (Retacrit®) on chemotherapy induced anemia response rate(a) and fatigue (FACIT-Fatigue)(b) at 16 weeks in elderly patients (aged 70 years and over) and to confirm the possible relationship between these two criteria.

Study Design

Non-interventional study design

Cohort

Population studied

Age groups

- Adults (65 to < 75 years)
- Adults (75 to < 85 years)
- Adults (85 years and over)

Estimated number of subjects

554

Study design details

Outcomes

To determine the impact of an ESA biosimilar (Retacrit®) on performance status at 16 weeks.To assess the modalities of use of an ESA biosimilar (Retacrit®) and its safety on this specific population.

Data analysis plan

Quantitative variables will be described (distribution) in terms of numbers, missing data, mean, standard deviation, median and range. Qualitative variables will be described (distribution) in terms of absolute frequency and percentage per class. The percentage of each type of response will be provided when the variable can take different forms (treatments, adverse events...). The number of missing data will be provided for each variable (the missing data will not be included in the calculation of percentages). In case of comparative analysis, it will be performed with a significance level set at 5% using: The Pearson Chi2 test for qualitative variables. The Student t-test or ANOVA for Gaussian quantitative variables. The non-parametric Mann-Whitney or Kruskal-Wallis test for semi-quantitative or non-Gaussian quantitative variables.

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

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