

FAST - Pharmaco-epidemiological observational study of the clinical benefit of Neorecormon® in cancer patients with anaemia, according to early response to treatment

Head :Roche Medical Data Center

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General

Identification

Detailed name Pharmaco-epidemiological observational study of the clinical benefit of Neorecormon® in cancer patients with anaemia, according to early response to treatment

Sign or acronym FAST

General Aspects

Medical area Cancer research

Study in connection with Covid-19 No

Pathology (details) Solid tumor or hematological malignancy

Health determinants Medicine

Keywords Epoetin beta

Scientific investigator(s) (Contact)

Name of the director Roche Medical Data Center

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Organization Roche SAS

Collaborations

Participation in projects, networks and consortia No

Funding

Funding status Private

Governance of the database

Sponsor(s) or organisation(s) responsible Roche SAS

Organisation status Private

Presence of scientific or steering committees Yes

Additional contact

Name of the contact <https://www.roche.fr/fr/innovation-recherche-medicale/data-sharing-portail-d-information-partage-des-donnees.html>

Main features

Type of database

Type of database Study databases

Study databases (details) Cohort study

Database recruitment is carried out by an intermediary A selection of health institutions and services

Database recruitment is made on the basis of: Medication(s) taken

Database recruitment is carried out as part of an interventional study No

Database objective

Main objective

Primary objective: To describe in real-life conditions the clinical benefit (i.e. transfusion sparing, maintenance of general health status, and professional and social activities) of NeoRecormon® in anaemic cancer patients, according to early response to treatment.

- Early response to NeoRecormon® was defined as an increase of hemoglobin concentration of at least 1 g/dL, 4 to 6 weeks after treatment initiation.

Secondary objectives:

In the total population and in each sub-population of patients [type of pathology (solid tumor, hematological malignancy or autograft), cancer pathology]:

1. to describe patients' characteristics at inclusion;

2. to describe the use of NeoRecormon® and the compliance to current guidelines [Market Authorization (MA), EORTC];
3. to describe the evolution of hemoglobin (Hb) level;
4. to describe the evolution of iron status and vitamin supplementation;
5. to describe Adverse Events (AEs) and serious AEs (targeted and non-targeted AEs).

Inclusion criteria

Inclusion criteria:

- Adult patient (aged ≥ 18 years);
- Patient receiving myelosuppressive chemotherapy (with or without radiotherapy) for solid tumor (breast, colorectal, lung, ovary), hematological malignancy (multiple myeloma, CLL, lymphoma), or autograft for hematological malignancy;
- Patient without erythropoiesis-stimulating agents (ESA) treatment, neither RBC transfusion within 4 weeks before enrollment;
- Patient for whom the physician had decided to initiate NeoRecormon® treatment at the inclusion visit;
- Patient's life expectancy ≥ 6 months according to the physician's opinion;
- Patient accepting and able to complete a French written questionnaire about his/her professional and social activities at 4 visits,
- Patient who received about the study both oral and written information and who did not object to his/her personal data being processed.

Exclusion criteria:

- None.

Population type

Age

Adulthood (19 to 24 years)
 Adulthood (25 to 44 years)
 Adulthood (45 to 64 years)
 Elderly (65 to 79 years)
 Great age (80 years and more)

Population covered

Sick population

Pathology

II - Neoplasms

Gender

Male
 Woman

Geography area

National

Data collection

Dates

Date of first collection (YYYY or MM/YYYY) 2010

Date of last collection (YYYY or MM/YYYY) 2010

Size of the database

Size of the database (number of individuals) [1000-10 000[individuals

Details of the number of individuals 1057

Data

Database activity Data collection completed

Type of data collected
Clinical data
Declarative data
Biological data

Clinical data (detail) Medical registration

Details of collected clinical data
Certificate attesting that the patient had been informed about the study - Eligibility criteria - Patient's current professional activity - Demographics - History of the disease - Anti-tumour therapy - Concomitant medication - Karnofsky Performance Status - Blood biochemistry (Hb, ferritin, BUN, reticulocytes, serum iron, CRP albumin, TSAT) - Assessment of anaemia management - Cancer treatments - Blood transfusion - Adverse events - Sick leave and number of days off sick during the study. PROs: Physical signs of anaemia - Work Productivity and Activity Impairment Questionnaire: General Health V2.0.

Declarative data (detail) Paper self-questionnaire

Presence of a biobank No

Health parameters studied Health care consumption and services

Care consumption (detail) Medicines consumption

Procedures

Data collection method paper CRF

Classifications used	CDISC
Quality procedure(s) used	GCP/GVP
Participant monitoring	Yes
Monitoring procedures	Monitoring by contact with the referring doctor
Links to administrative sources	No

Promotion and access

Promotion

Access

Dedicated website	https://www.roche.fr/fr/innovation-recherche-medicale/data-sharing-portail-d-information-partage-des-donnees.html
Presence of document that lists variables and coding procedures	Yes
Access to aggregated data	Access on specific project only
Access to individual data	Access on specific project only