FAST - Pharmaco-epidemiological observational study of the clinical beneft 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 beneft 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
Address	4 cours de l'Ile Seguin - 92650 BOULOGNE-BILLANCOURT
Email	data_sharing_france@roche.com
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 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