# 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

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|---|---|
| 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

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| 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)

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|---|---|
| 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

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|---|---|
| Participation in projects, networks and consortia | No |

### Funding

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|---|---|
| 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.<br>- 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.<br><br>Secondary objectives:<br>In the total population and in each sub-population of patients [type of pathology (solid tumor, hematological malignancy or autograft), cancer pathology]:<br>1. to describe patients' characteristics at inclusion; |

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| | 2. to describe the use of NeoRecormon® and the compliance to current guidelines [Market Authorization (MA), EORTC];<br>3. to describe the evolution of hemoglobin (Hb) level;<br>4. to describe the evolution of iron status and vitamin supplementation;<br>5. to describe Adverse Events (AEs) and serious AEs (targeted and non-targeted AEs). |
| Inclusion criteria | Inclusion criteria:<br>- Adult patient (aged >= 18 years);<br>- 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;<br>- Patient without erythropoiesis-stimulating agents (ESA) treatment, neither RBC transfusion within 4 weeks before enrollment;<br>- Patient for whom the physician had decided to initiate NeoRecormon® treatment at the inclusion visit;<br>- Patient's life expectancy ? 6 months according to the physician's opinion;<br>- Patient accepting and able to complete a French written questionnaire about his/her professional and social activities at 4 visits,<br>- Patient who received about the study both oral and written information and who did not object to his/her personal data being processed.<br><br>Exclusion criteria:<br>- None. |
| **Population type** | |
| Age | Adulthood (19 to 24 years)<br>Adulthood (25 to 44 years)<br>Adulthood (45 to 64 years)<br>Elderly (65 to 79 years)<br>Great age (80 years and more) |
| Population covered | Sick population |
| Pathology | II - Neoplasms |
| Gender | Male<br>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<br>Declarative data<br>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 |

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| 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

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|---|---|
| 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 |