

COMETE - A non-interventional study to assess the hemoglobin level depending on the comorbidity index in chronic kidney disease (CKD) patients not on dialysis treated with Mircera®

Head :Roche Medical Data Center

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General

Identification

Detailed name A non-interventional study to assess the hemoglobin level depending on the comorbidity index in chronic kidney disease (CKD) patients not on dialysis treated with Mircera®

Sign or acronym COMETE

CNIL registration number, number and date of CPP agreement, AFSSAPS (French Health Products Safety Agency) authorisation ML28145

General Aspects

Medical area Urology, andrology and nephrology

Study in connection with Covid-19 No

Pathology (details) Chronic Kidney Disease not on dialysis

Health determinants Iatrogenic Medicine

Keywords MIRCERA®

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

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|----------------|---|
| Main objective | <p>Primary objective : Describe in current medical practice the evolution of hemoglobin levels during the 9-month follow-up in each subgroup defined by the Charlson comorbidity index.</p> <p>Secondary objectives :</p> <ul style="list-style-type: none">- Describe the characteristics of patients treated with Mircera® in the total population and in the subgroups defined by the Charlson comorbidity |
|----------------|---|

index;

- Describe the evolution of the hemoglobin level during the observation period according to the Liu comorbidity index and to ESA resistance factors;
- Describe the changes in the Mircera® dosage during the observation period in the total population and in the subgroups defined by the Charlson comorbidity index;
- Describe the safety profile of Mircera® during the observation period in the total population and in the subgroups defined by the Charlson comorbidity index.

Inclusion criteria

Inclusion criteria :

- Patient ≥ 18 years of age;
- Patient with chronic kidney disease not on dialysis;
- ESA-naïve patients (not having received ESAs within the 6 months prior to inclusion);
- Patients with hemoglobin level < 10.0 g/dL at inclusion;
- Patients for whom the treating physician has decided to initiate treatment with Mircera® for medical reasons prior to study start;
- Patient having received both oral and written information about the study, without any objections for the use of his/her personal data.

Non inclusion criteria :

- Patients with functional renal transplant;
- Patients participating in a clinical trial on anemia due to CKD.

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

N18 - Chronic kidney disease

Gender

Male
Woman

Geography area

National

Data collection

Dates

| | |
|--|--|
| Date of first collection (YYYY or MM/YYYY) | 2012 |
| Date of last collection (YYYY or MM/YYYY) | 2015 |
| Size of the database | |
| Size of the database (number of individuals) | [500-1000[individuals |
| Details of the number of individuals | 550 |
| Data | |
| Database activity | Data collection completed |
| Type of data collected | Clinical data Biological data |
| Clinical data (detail) | Medical registration |
| Details of collected clinical data | Validation of inclusion and exclusion criteria - Dates of visits (or data of last contact with the patient) - Demographic - CKD history and evolution - Comorbidities - Most recent clinical and biological data - Previous and/or ongoing CKD treatments - Other specific treatments - Previous and/or ongoing anemia treatments - Treatment with Micera® - Adverses events - Reason for early study discontinuation. |
| Presence of a biobank | No |
| Health parameters studied | Health event/morbidity Health event/mortality Health care consumption and services |
| Care consumption (detail) | Medicines consumption |
| Procedures | |
| Data collection method | eCRF |
| 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