# 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

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| 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

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|---|---|
| Medical area | Urology, andrology and nephrology |
| Study in connection with Covid-19 | No |
| Pathology (details) | Chronic Kidney Disease not on dialysis |
| Health determinants | Iatrogenic<br>Medicine |
| Keywords | MIRCERA® |

### 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

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

## Funding

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|---|---|
| Funding status | Private |

## Governance of the database

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| 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

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|---|---|
| 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

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| Main objective | 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.<br><br>Secondary objectives :<br>- Describe the characteristics of patients treated with Mircera® in the total population and in the subgroups defined by the Charlson comorbidity |

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| | index;<br>- Describe the evolution of the hemoglobin level during the observation period according to the Liu comorbidity index and to ESA resistance factors;<br>- 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;<br>- 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 :<br>- Patient >=18 years of age;<br>- Patient with chronic kidney disease not on dialysis;<br>- ESA-naive patients (not having received ESAs within the 6 months prior to inclusion);<br>- Patients with hemoglobin level <10.0 g/dL at inclusion;<br>- Patients for whom the treating physician has decided to initiate treatment with Mircera® for medical reasons prior to study start;<br>- Patient having received both oral and written information about the study, without any objections for the use of his/her personal data.<br><br>Non inclusion criteria :<br>- Patients with functional renal transplant;<br>- Patients participating in a clinical trial on anemia due to CKD. |
| **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 | N18 - Chronic kidney disease |
| Gender | Male<br>Woman |
| Geography area | National |
| **Data collection** | |
| **Dates** | |

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|---|---|
| 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<br>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<br>Health event/mortality<br>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 |

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| 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 |