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
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 : 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. Secondary objectives : - 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-naive 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