MIRIADE - Impact of comorbidities on hemoglobin stability in chronic kidney disease patients on dialysis treated with C.E.R.A

Head :Roche Medical Data Center

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General

Identification

Detailed name	Impact of comorbidities on hemoglobin stability in chronic kidney disease patients on dialysis treated with C.E.R.A
Sign or acronym	MIRIADE

General Aspects

Medical area	Urology, andrology and nephrology
Study in connection with Covid-19	No
Pathology (details)	Chronic Kidney Disease on hemodialysis or hemofiltration
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: To describe in CKD patients on dialysis the impact of comorbidities* on hemoglobin stability** after 6 months of treatment with Mircera® in routine clinical practice * Patients' comorbidities will be analyzed on the basis of the CCI. ** Hemoglobin stability is defined as a variation of +/- 1g/dL of hemoglobin level between the first Mircera® injection and the 6th month of treatment, without red blood cells transfusion during this period. Secondary objectives: - In the overall study population and in each subgroup of patients defined by a range of the Charlson comorbidity index (<=3, [4-5], [6-7],

	>=8): - - To describe baseline characteristics of the patients; - - To describe the monthly changes in hemoglobin level; - - To describe monthly Mircera® dose. - To describe patients' vital status and all adverse events over the observation period with Mircera®; - To describe the hemoglobin stability after 6 months of treatment with Mircera®, according to subgroups of Liu comorbidity index (<=3; [4-6]; [7-9]; >=10); - To describe the proportion of patients with an Hb level within the range 10-12 g/dL with or without hemoglobin stability after 6 months of treatment with Mircera®, according to the subgroups of Charlson and Liu comorbidity indexes.
Inclusion criteria	Inclusion criteria: - Patient aged 18 years or older; - CKD patient on hemodialysis or hemodiafiltration for at least 3 months; - Patient previously treated with an ESA; - Patient for whom the investigator decided to initiate a treatment with Mircera® for medical reasons; - Patient with last hemoglobin level within the range [10 – 12] g/dL before Mircera® initiation; - Patient having received oral and written information about the study, without any objections for the use of his/her personal data, and having signed a written informed consent form. Exclusion criteria: - Patients participating in a clinical trial on renal anemia at inclusion were excluded from study entry.
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)	2014
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	636
Data	
Database activity	Data collection completed
Type of data collected	Clinical data Biological data
Clinical data (detail)	Medical registration
Details of collected clinical data	Demographic - Disease History - Comorbidities - Biology - Previous anemia treatments - Concomitant anemia treatments - Adverse Events.
Presence of a biobank	No
Health parameters studied	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