HORTENSIA - Cohort study in chronic kidney disease patients on dialysis starting treatment with Mircera® to correct anemia or maintain stable hemoglobin levels

Head :Roche Medical Data Center

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General

Identification

Detailed name	Cohort study in chronic kidney disease patients on dialysis starting treatment with Mircera® to correct anemia or maintain stable hemoglobin levels
Sign or acronym	HORTENSIA

General Aspects

Medical area	Urology, andrology and nephrology
Study in connection with Covid-19	No
Pathology (details)	Chronic Kidney Disease 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	Public
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 the management of anemia treatment with Mircera® in routine clinical practice in chronic kidney disease patients on dialysis and to describe their hemoglobin concentration around the 6th month of treatment with Mircera®. Secondary objective: In the total population and in each sub-population of patients (hemodialysis and peritoneal dialysis, ESA-naive and non ESA-naive patients): 1. Describe the characteristics of patients treated with Mircera®; 2. Describe the evolution of Hb and hematocrit levels during the observation period; 3. Describe the biological parameters used to

	document renal anemia and any changes in values; 4. Describe the parameters influencing treatment response; 5. Describe the biological parameters reflecting the efficacy of dialysis; 6. Describe the safety profile of Mircera® (serious and/or unexpected adverse drug reactions and targeted adverse drug reactions related to Mircera®); 7. Describe treatment compliance with Mircera®; 8. Describe the evolution of patients' quality of life, evaluated by the SF-36 questionnaire.
Inclusion criteria	Inclusion criteria: - Adult (aged >= 18 years); - With CKD and on dialysis for more than 3 months; - ESA-naive or not; - For whom the physician decided to initiate treatment with Mircera® for renal anemia at the inclusion visit; - Who was informed about the study both orally and in writing and who did not object to their personal data being processed. Exclusion criteria: - Patient participating in a clinical study; - Anemia due to a malignant disease.
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)	2010
Date of last collection (YYYY or	2011

MM/YYYY)	
Size of the database	
Size of the database (number of individuals)	< 500 individuals
Details of the number of individuals	414
Data	
Database activity	Data collection completed
Type of data collected	Clinical data Biological data
Clinical data (detail)	Medical registration
Details of collected clinical data	Patient provided with information about the study - Demographic and clinical data, concomitant diseases - History of chronic renal failure and dialysis - Previous treatment for CKD-associated anemia: with ESA if any and other potential treatments (iron, folic acid, vitamin B12, blood transfusion over the last 3 months before Mircera® initiation) - Clinical data at the midweek dialysis session: weight after the session, blood pressure at rest and after the session - Most recent available laboratory data: urea and serum creatinine (before and after the dialysis session), urea reduction ratio, Kt/V (hemodialysis), total Kt/V (peritoneal dialysis), Hb, hematocrit, platelet count, reticulocytes, iron status, C-reactive protein, documented deficiency in folic acid or vitamin B12 if any - Treatment of CKD-associated anemia at inclusion: treatment with Mircera® and concomitant treatment if any (iron, folic acid, vitamin B12) - Other treatments: antihypertensives, antiplatelet drugs, anticoagulants, LMWH, lipid-lowering treatments, antidiabetics, immunosuppressors.
Presence of a biobank	No
Health parameters studied	Health care consumption and services
Care consumption (detail)	Medicines consumption
Procedures	
Data collection method	paper
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