OPTICERA - Identification of factors allowing a therapeutic anemia management optimization in CKD patients treated with C.E.R.A.

Head :Roche Medical data center

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General

Identification

Detailed name	Identification of factors allowing a therapeutic anemia management optimization in CKD patients treated with C.E.R.A.
Sign or acronym	OPTICERA
CNIL registration number, number and date of CPP agreement, AFSSAPS (French Health Products Safety Agency) authorisation	ML39300

General Aspects

Medical area	Urology, andrology and nephrology
Study in connection with Covid-19	No
Pathology (details)	Anemia in Chronic Kidney Disease
Health determinants	Medicine
Keywords	Méthoxy-polyéthylène glycol-époétine bêta

Scientific investigator(s) (Contact)

Name of the director	Roche Medical data center
Address	4 cours de l'Ile Seguin - 92100 Boulognne-Billancourt
Email	data_sharing.france@roche.com
Organization	Roche SAS

Collaborations

Participation in projects,	No

networks and consortia

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

Main features

Type of database

Type of database	Study databases
Study databases (details)	Longitudinal study (except cohorts)
Database recruitment is carried out by an intermediary	A selection of health care professionals
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 identify the potential factors of optimizing the therapeutic management of renal anemia with C.E.R.A. Secondary Objectives: - Analysis of the therapeutic response to C.E.R.A., according to 4 definitions (reach or maintenance of the Hb concentration within the therapeutic target range of [10-12] g/dL, limitation of Hb variability at +/- 1 g/dL from the baseline value, both above criteria, or at least one of the above criteria, after a 3-month treatment period) - Description of patient and disease characteristics at first C.E.R.A. injection - Description of the evolution of CKD management (physical examination, laboratory parameters

	including Hb values and renal function, prior and ongoing concomitant treatments for anemia, as well as concomitant diseases and treatments) under C.E.R.A. treatment - Search for any associations/correlations between variables and detection of particular profiles.
Inclusion criteria	Inclusion criteria: - CKD patients having started C.E.R.A. treatment at inclusion - With at least one Hb value within the 3-month period prior to the first C.E.R.A. injection - With no participation in an interventional study

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	D63 - Anaemia in chronic diseases classified elsewhere
Gender	Male Woman
Geography area	National

Data collection

Dates

Date of first collection (YYYY or MM/YYYY)	2009
Date of last collection (YYYY or MM/YYYY)	2015

Size of the database

Size of the database (number of individuals)	[1000-10 000[individuals
Details of the number of individuals	2984

Data

Database activity	Data collection completed

Type of data collected	Clinical data
Clinical data (detail)	Medical registration
Details of collected clinical data	Pooling of 5 non-interventional studies with Mircera® (OCEANE / HORTENSIA / COMETE / PERCEPOLIS / MIRIADE). Type of data collected : demographics, comorbidities, CKD history, prior treatments for anemia, laboratory data, first C.E.R.A. injection, other treatments, vital signs, treatment for anemia, C.E.R.A. injections, other treatments, early withdrawal.
Presence of a biobank	No

Procedures

Data collection method	Pool of 5 non interventional databases
Classifications used	CDISC like
Quality procedure(s) used	GCP/GVP
Participant monitoring	Yes
Monitoring procedures	Monitoring by contact with the referring doctor
Followed pathology	N18 - Chronic kidney disease
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