SANTORIN - Monitoring antiangiogenic agents in real-life conditions of use for renal cancer

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General

Identification

Detailed name	Monitoring antiangiogenic agents in real-life conditions of use for renal cancer
Sign or acronym	SANTORIN
CNIL registration number, number and date of CPP agreement, AFSSAPS (French Health Products Safety Agency) authorisation	CCTI-RS 08.023, CNIL 908094

General Aspects

Medical area	Cancer research
Health determinants	Iatrogenic Medicine
Keywords	Metastatic renal cancer, antiangiogenic, first line, toxicity, tolerance, survival, conditions of use, targeted therapy, pharmacoepidemiology, cohort, Department of Pharmacology, Bordeaux

Scientific investigator(s) (Contact)

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Unit	Service de Pharmacologie, CIC-P 0005-INSERM U657- Université Bordeaux Segalen
Organization	Université Bordeaux
Collaborations	
Participation in projects, networks and consortia	No
Funding	
Funding status	Mixed
Details	Pfizer France (unconditional support)
Governance of the database	
Sponsor(s) or organisation(s) responsible	Service de Pharmacologie, CIC-P 0005-INSERM U657- Université Bordeaux Segalen
Organisation status	Public
Presence of scientific or steering committees	Yes
Additional contact	
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
Additional information regarding sample selection.	Patients were included retrospectively on the 1 January 2008 or prospectively from this date by hospital physicians prescribing antiangiogenic agents.

Database objective

Main objective	The main objective is to estimate the overall survival at 24 months of patients with metastatic renal cancer, treated by first line antiangiogenic agents in real-life and investigate (for products for which sufficient data have been collected) if this differs from that reported in pivotal clinical trials that contributed to market authorisation.
Inclusion criteria	Patient with metastatic renal cancer receiving first-line treatment who began treatment with antiangiogenic agent during the inclusion period (whether or not treatment was continued or not); Patient previously unexposed to antiangiogenic agent, including during a clinical trial or Temporary Authorisation for Use; Patient able to be followed for 2 years; Patient treated with an antiangiogenic agent marketed more than 6 months in France; Patient not participating in a clinical trial; Patient not affected by a language barrier (unable to read the information letter or complete the self-administered questionnaire); Patient not objecting to data collection.

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	C00-C75 - Malignant neoplasms, stated or presumed to be primary, of specified sites, except of lymphoid, haematopoietic and related tissue
Gender	Male Woman

Geography area	National
Detail of the geography area	Hospital physicians prescribing antiangiogenic agents in France

Data collection

Dates

Date of first collection (YYYY or MM/YYYY)	05/2009
Date of last collection (YYYY or MM/YYYY)	05/2012

Size of the database

Size of the database (number of individuals)	[500-1000[individuals
Details of the number of individuals	522 patients identifiés, 390 patients inclus - 522 patients identified, of which 390 patients were included

Data

Database activity	Data collection completed
Type of data collected	Clinical data Declarative data
Clinical data (detail)	Direct physical measures
Declarative data (detail)	Paper self-questionnaire
Presence of a biobank	No
Health parameters studied	Health event/morbidity Health event/mortality Health care consumption and services Quality of life/health perception
Care consumption (detail)	Hospitalization Medical/paramedical consultation Medicines consumption

Procedures

Data collection method	Clinical and antiangiogenic agent use data are collected from two sources: medical records of centres responsible for monitoring of patients (eCRF complemented by an CRA) and patient paper-

	based self-administered questionnaire.
Participant monitoring	Yes
Details on monitoring of participants	Continuous monitoring of first-line metastatic renal cancer treatment for up to 24 months. Data will be collected at 24 months for all patients including those who have had multiple lines of therapy (data regarding the treatment of disease, survival data).
Links to administrative sources	No
Promotion and access	
Promotion	
Link to the document	https://www.ncbi.nlm.nih.gov/pubmed/28573786
Access	
Terms of data access (charter for data provision, format of data, availability delay)	A study report was delivered to the pharmaceutical company after validation by the study Scientific Committee. Scientific articles are currently being drafted.. Ownership of study data is the subject of an agreement between the University of Bordeaux Segalen and the pharmaceutical company. Terms for third-party access to the database are to be defined.
Access to aggregated data	Access on specific project only
Access to individual data	Access on specific project only