EPHEGREN - Longitudinal Pharmacoeconomical Study on Kidney Transplantation Patients

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General

Identification

Detailed name	Longitudinal Pharmacoeconomical Study on Kidney Transplantation Patients
Sign or acronym	EPHEGREN
CNIL registration number, number and date of CPP agreement, AFSSAPS (French Health Products Safety Agency) authorisation	CNIL DR-2012-476

General Aspects

Medical area	Urology, andrology and nephrology
Keywords	immunosuppressive strategies (IS), kidney transplants, assessment, impact, health insurance

Scientific investigator(s) (Contact)

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Collaborations

Funding

Funding status	Public
Details	2011 Interregional Hospital Clinical Research Programme (PHRC), Limoges University Hospital Centre (UHC).

Governance of the database

Sponsor(s) or organisation(s) responsible	CHU Limoges
Organisation status	Public

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 A selection of health institutions and services
Database recruitment is is made on the basis of:	Another treatment or procedure
Database recruitment is carried out as part of an interventional	No

study	
Additional information regarding sample selection.	700 de novo renal transplant patients and 300 patients from a previous cohort of kidney transplant recipients

Database objective

Main objective	The main aim of the EPHEGREN study is to assess the pharmacoeconomic impact of different immunosuppressive strategies (IS) on kidney transplant patients from a hospital, health insurance and societal perspective. The secondary objectives of the EPHEGREN study: To assess the cost-effectiveness of different preventative and curative strategies for reactivation and cytomegalovirus (CMV) disease in CMV+ kidney transplant patients (serologic status of recipient when receiving transplant) from a hospital, health insurance and societal perspective. To determine predictive pharmacological factors for long-term renal function outcome. To determine predictive pharmacological factors for the onset of cancer, diabetes and cardiovascular diseases. To validate the impact of genetic polymorphisms on metabolic enzymes, membrane transporters and proteins targeting immunosuppressants on exposure and the therapeutic and side effects of treatment. To prospectively validate urinary biomarker candidates for current or future acute rejection, or for chronic renal allograft dysfunction.
Inclusion criteria	Adult patients from both sexes during the first month of kidney transplantation who are able to complete the study questionnaire.

Population type

Age	Adulthood (19 to 24 years) Adulthood (25 to 44 years) Adulthood (45 to 64 years)
Population covered	Sick population
Pathology	Z94 - Transplanted organ and tissue status
Gender	Male Woman
Geography area	National

Detail of the geography area	6 hospitals (Limoges, Bordeaux, Toulouse, Rouen, Poitiers and Amiens).

Data collection

Dates

Date of first collection (YYYY or MM/YYYY)	2013
Date of last collection (YYYY or MM/YYYY)	2017

Size of the database

Size of the database (number of individuals)	[500-1000[individuals
Details of the number of individuals	1,000

Data

Database activity	Data collection completed
Type of data collected	Clinical data Declarative data Administrative data
Clinical data (detail)	Direct physical measures
Declarative data (detail)	Paper self-questionnaire
Presence of a biobank	Yes
Contents of biobank	Whole blood Fluids (saliva, urine, amniotic fluid, ?)
Details of biobank content	Other fluids (saliva, urine, amniotic fluid, etc.).
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

Procedures

Data collection method	In the patient medical file and from a patient questionnaire: on observance, adverse effects and

	quality of life, and socio-demographic datas
Classifications used	adverse events coded with MEDDRA
Quality procedure(s) used	eCRF developped with ENNOV CLINICA
Participant monitoring	Yes
Monitoring procedures	Monitoring by contact with the referring doctor
Details on monitoring of participants	1, 3, 6, 12, 18, 24 months post-transplantation and then annually.
Followed pathology	Z94 - Transplanted organ and tissue status
Links to administrative sources	Yes
Linked administrative sources (detail)	DIM for medico-economic datas (PMSI)

Promotion and access

Promotion

Access

Terms of data access (charter for data provision, format of data, availability delay)	Conditions for access to the database is being defined.
Access to aggregated data	Access on specific project only
Access to individual data	Access on specific project only