

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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Organization	CHU

Collaborations

Funding

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

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

Additional contact

Main features

Type of database	Study databases
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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
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Database recruitment is made on the basis of:	Another treatment or procedure
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Database recruitment is carried out as part of an interventional	No
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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