SURDIAGENE - Genetic Polymorphism in Subjects with Type 2 Diabetes and Longitudinal Analysis of Renal Function: ? SURDIAGENE? Study (SUivi Rénal , DIAbète de type 2 et GENEtique)

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General

Identification

Detailed name	Genetic Polymorphism in Subjects with Type 2 Diabetes and Longitudinal Analysis of Renal Function: ?SURDIAGENE? Study (SUivi Rénal , DIAbète de type 2 et GENEtique)
Sign or acronym	SURDIAGENE
CNIL registration number, number and date of CPP agreement, AFSSAPS (French Health Products Safety Agency) authorisation	CPP : N°03.10.19 du 24/11/2003 ; DGS 2003/0530 du 15/12/2003 ; CNIL : en attente

General Aspects

Medical area	Endocrinology and metabolism Urology, andrology and nephrology
Health determinants	Genetic Medicine Nutrition
Keywords	Health episodes, renal function, cardiovascular, death, population, health system

Scientific investigator(s) (Contact)

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Unit	CIC 1402
Organization	CHU Poitiers

Collaborations

Participation in projects, networks and consortia	Yes

Funding

Funding status	Mixed
Details	PHRC régional 2000 / PHRC interrégional 2004 / association GEMMS

Governance of the database

Sponsor(s) or organisation(s) responsible	CHU de Poitiers
Organisation status	Public

Additional contact

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Unit	Biobank
Organization	CHU Poitiers

Main features

Type of database

Type of database	Study databases
Study databases (details)	Cohort study
Database recruitment is carried	A selection of health institutions and services

out by an intermediary	
Database recruitment is carried out as part of an interventional study	No
Additional information regarding sample selection.	Prospective Inclusion cut-off date: 01/01/2009 Number of required subjects: [1,000-5,000] Details regarding this number: Initial calculation based on data from genotype frequency less relevant in 2009 compared to 2002 (date of conception).

Database objective

Main objective	MAIN: to investigate the genetic determinants associated with changes in renal function (changes in creatinine clearance) SECONDARY: 1. - to investigate the genetic determinants associated with changes in urinary albumin excretion 2 - to investigate the genetic determinants associated with other degenerative complications of diabetes (retinopathy, cardiovascular events)
Inclusion criteria	B1. Type 2 diabetes (T2D): Subjects from the SURDIAGENE study with T2D. The distinction between type 1 (TD1) and type 2 (T2D) diabetes is sometimes difficult. We define criteria for T2D diagnosis as: - age at diagnosis is 35 years old or over - apparent insulin-dependence after more than 2 years following diabetes diagnosis - absence of secondary diabetes - absence of ketonuria at diagnosis B2: Longitudinal follow-up: Subjects in the SURDIAGENE study with T2D who are being monitored for diabetes for at least one year, which includes a collection of clinical (blood pressure, weight) and biological data (glycated haemoglobin, serum creatinine, urinary albumin excretion) to analyse the progression of renal disease and other degenerative (retinal and cardiovascular) complications B3. Exclusion criteria is defined as: Subjects who are not permitted to participate in the SURDIAGENE study are subjects who a) fulfil medical criteria for exclusion - do not have diabetes or have T1D or secondary diabetes - are presenting renal disease caused by non-diabetic renal insufficiency (arterial hypertension is not considered as part of the exclusion criteria, except if hypertensive nephropathy precedes discovery of diabetes). - proteinuria at time of diabetes diagnosis - non-diabetic glomerular nephropathy confirmed by renal biopsy - pure vascular nephropathy - confirmed glomerular haematuria or malformed uropathy - chronic interstitial nephritis with history

of pyelonephritis or persistent urinary tract infections - follow-up is less than 1 year b) fulfilling legal exclusion criteria (amended law dated 20th December 1988) - minors - adults protected by law - deprived of liberty - brain-dead - who have not given their written participation consent - women who are pregnant, parturient or breastfeeding - not affiliated to social security

Population type

Age	Adulthood (25 to 44 years) Adulthood (45 to 64 years) Elderly (65 to 79 years)
Population covered	Sick population
Pathology	E11 - Type 2 diabetes mellitus
Gender	Male Woman
Geography area	Local
Detail of the geography area	Poitiers (Vienne)

Data collection

Dates

Date of first collection (YYYY or MM/YYYY)	12/2003
Date of last collection (YYYY or MM/YYYY)	2020

Size of the database

Size of the database (number of individuals)	[1000-10 000[individuals
Details of the number of individuals	1200

Data

Database activity	Current data collection
Type of data collected	Clinical data Biological data
Clinical data (detail)	Direct physical measures

	Medical registration
Biological data (detail)	Renal function and glycaemic control: Renal function is based on a measurement of plasma creatinine and estimated glomerular filtration rate (GFR estimated by MDRD and CKD-EPI equations). Diabetic renal insufficiency (initial and during follow-up) is equally characterised by urinary albumin excretion and urinary albumin/urinary creatinine ratio. The level of renal impairment as well as GFR can be established as such. Glycaemic control rate is calculated by measuring glycated haemoglobin (HbA1c).
Presence of a biobank	Yes
Contents of biobank	Serum Plasma DNA Others
Details of biobank content	Other: urine, buffy coat
Health parameters studied	Health event/morbidity Health event/mortality

Procedures

Data collection method	Interview: input from a paper questionnaire (manual input) with double entry Clinical examinations: handwritten (manual input) with double data entry Biological analysis: direct input
Participant monitoring	Yes
Details on monitoring of participants	Follow-up duration: 10 years
Links to administrative sources	Yes
Linked administrative sources (detail)	CépiDC

Promotion and access

Promotion

Link to the document	http://www.ncbi.nlm.nih.gov/pubmed/?term=SURDIAGENE
Description	List of publications in Pubmed
Link to the document	Surdiagene.pdf

Access

Terms of data access (charter for data provision, format of data, availability delay)	Send request to scientist in charge
Access to aggregated data	Access on specific project only
Access to individual data	Access on specific project only