ISIS-DIAB - French Multicentric Cohort on Genetic, Epigenetic and Environmental Risk Factors of Autoimmune Diabetes and its Complications.

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Général

Identification

Nom détaillé	French Multicentric Cohort on Genetic, Epigenetic and Environmental Risk Factors of Autoimmune Diabetes and its Complications.
Sigle ou acronyme	ISIS-DIAB
Numéro d'enregistrement (ID-RCB ou EUDRACT, CNIL, CPP, etc.)	CNIL n°909186, DR-2010-0035 / CPPn°DC-2008-693, NI 2620 09/12/2008 / CCTIRS n°08.402 11/09/2008

Thématiques générales

Domaine médical	Endocrinology and metabolism
Déterminants de santé	Climate Genetic Geography Nutrition Occupation Pollution Social and psychosocial factors
Mots-clés	Genetic environment

Responsable(s) scientifique(s)

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Organisme	INSERM - Institut National de la Santé et de la Recherche

Collaborations

Financements

Financements	Mixed
Précisions	Inserm/NovoNordisk (ALLIANCE)

Gouvernance de la base de données

Organisation(s) responsable(s) ou promoteur	INSERM - Institut National de la Santé et de la Recherche Médicale
Statut de l'organisation	Secteur Public

Contact(s) supplémentaire(s)

Caractéristiques

Type de base de données

Type de base de données	Study databases
Base de données issues d'enquêtes, précisions	Cohort study

Origine du recrutement des participants	A selection of health institutions and services
Le recrutement dans la base de données s'effectue dans le cadre d'une étude interventionnelle	No
Informations complémentaires concernant la constitution de l'échantillon	Cases are recruited from paediatric or diabetology departments who agreed to participate in the study.

Objectif de la base de données

Objectif principal	To conduct gene-environment studies on a large scale, with a "data driven" methodology (GWAS for the genetic portion, questionnaires with no preconceived ideas and French environmental databases for the environmental portion), in order to identify risk factors of type 1 diabetes as well as its acute (severe hypoglycaemia, ketoacidosis) and chronic (retinopathy, nephropathy) complications. To conduct epigenetic studies by investigating methylation development (candidate genes or the entire genome) according to different phenotypic traits (glycaemic control, onset of complications, insulin dosage).To be the basis of immune modulation studies for all early diabetes, or for patients resistant to autoimmune attack, and to keep a significant reserve of functional beta cells for 1-5 years (European project DF-IL2, through collaboration with D. Klatzman, funded by FP7 clinical trial tender). ISIS provides the infrastructure to enable the recruitment of newly diagnosed diabetes cases (149 new cases of diabetes recruited in 2008, 136 in 2009, 143 in 2010 and 191 in 2011). To investigate the beginning of microangiopathic complications in a significant number of children and to study the medical, genetic, epigenetic and environmental determinants of these complications by an integrated and multi-factorial approach. Patients currently in the ISIS cohort have had diabetes for an average of 10.8 years and a mean HbA1c of 8.4%. Background retinopathy is expected in approximately 20% of those that have had diabetes over 10 years (at present: 1,581 cohort patients have had diabetes for more than 10 years, approximately 300 patients are expected to develop complications). We also wish to initiate a strategy for prospective primary prevention trials for retinopathy in 2012 in collaboration with Prof. P. Massin. To conduct studies on conventional

	treatment and improvements that can be initiated. Our main focus is to test therapeutic education procedures that can limit inequalities in treatment quality and promote "minimally disruptive" medical practice (May C, Montori VM, Fair FS: We need minimally disruptive medicine, BMJ 2009; 339: b2803) capable of minimising the therapeutic burden added to chronic disease, in contrast with the rampant intensification of treatment practised by some that we believe now threatens the quality of psychological development of a significant proportion of young children with diabetes. To conduct prospective studies on sudden death syndrome, "dead in bed" characteristics of adolescents with diabetes (O'Reilly M, O'Sullivan EP, Davenport C, Smith D: « Dead in bed » : a tragic complication of type 1 diabetes mellitus, Ir J Med Sci 2010, 179 (4): 585-7), risk factors for mortality and morbidity in severe ketoacidosis (special youth complications). Such studies do not exist in the literature: important case-based reasoning is necessary to answer these two questions. This explains the limited nature of the studies in the literature that relied on a small series of anecdotal and retrospective cases. To conduct humanities and social science studies in the field of psychological consequences of childhood diabetes, including the frequency of depressive syndromes (patients and parents) and to analyse health care access disparities (incorporating geographical, medical and sociological analyses). To broaden the scope of cohort-related work by screening case families for diabetes (there are about 5,200 brothers or sisters under 7 years of age related to diabetic children already included in ISIS).
Critères d'inclusion	French people with type 1 diabetes
Type de population	
Age	Infant (28 days to 2 years) Early childhood (2 to 5 years) Childhood (6 to 13 years) Adolescence (13 to 18 years) 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 concernée	Sick population

Sexe	Male Woman
Champ géographique	National
Détail du champ géographique	France

Collecte

Dates

Année du premier recueil	2006

Taille de la base de données

Taille de la base de données (en nombre d'individus)	[10 000-20 000[individuals
Détail du nombre d'individus	10000

Données

Activité de la base	Current data collection
Type de données recueillies	Clinical data Declarative data Biological data
Données cliniques, précisions	Direct physical measures
Données déclaratives, précisions	Paper self-questionnaire Phone interview
Données biologiques, précisions	DNA
Existence d'une biothèque	Yes
Contenu de la biothèque	Plasma DNA
Détail des éléments conservés	Blood samples were pretreated: separation of plasma for plasma bank and lymphocytes for DNA extraction. Biobank is kept at -80°C.
Paramètres de santé étudiés	Health event/morbidity Health event/mortality

Modalités

Mode de recueil des données	Clinical data are collected in patient clinical records every 6 months from enrolment date Biological data collected at baseline (blood sample for DNA

	extraction and plasma bank, transportation at +4°C by a professional carrier, treatment and storage) environmental data collected through a questionnaire sent to patients in the month following their enrolment (+ telephone follow-up if needed)
Suivi des participants	Yes
Détail du suivi	Clinical parameter follow-up
Appariement avec des sources administratives	No

Valorisation et accès

Valorisation et accès

Lien vers le document	http://tinyurl.com/Pubmed-ISIS-DIAB
Description	List of publications in Pubmed

Accès

Charte d'accès aux données (convention de mise à disposition, format de données et délais de mise à disposition)	Contact the scientist in charge
Accès aux données agrégées	Access on specific project only
Accès aux données individuelles	Access on specific project only