RaDiCo-PID - Idiopathic Interstitial Pneumonia: From Infancy to Elderly

Responsable(s) :Cottin Vincent , Inserm UMR754

Date de modification : 03/12/2024 | Version : 2 | ID : 73380

Général

Identification

Nom détaillé	Idiopathic Interstitial Pneumonia: From Infancy to Elderly
Sigle ou acronyme	RaDiCo-PID
Numéro d'enregistrement (ID-RCB ou EUDRACT, CNIL, CPP, etc.)	CCTIRS n° 16.050Bis / CNIL Decision n° DR-2016-431

Thématiques générales

Domaine médical	Pediatrics Pneumology Radiology and medical imaging Rare diseases
Etude en lien avec la Covid-19	No
Pathologie, précisions	Idiopathic Interstitial Pneumonia: Idiopathic Interstitial Pneumonia (IIP), known in French as ? Pneumopathies Interstitielles Diffuses (PID)? and referred in the current protocol as IPP/PID, encompass a group of diffuse infiltrative lung diseases of unknown origin that affect the lung architecture and are characterized by a progressive and often irreversible remodeling of the lung. Clinical expression includes mainly dyspnea, restriction on pulmonary function testing, impaired haematosis and radiologic diffuse lung infiltration. In most situations, these diffuse lung disorders are chronic, with high morbidity and mortality due to the lack of curative therapy.
Déterminants de santé	Climate Genetic Healthcare system and access to health care services Lifestyle and behavior Medicine Occupation Pollution Social and psychosocial factors

Responsable(s) scientifique(s)	
Nom du responsable	Cottin
Prénom	Vincent
Adresse	Hôpital Louis Pradel, Hospices Civils de Lyon Service de pneumologie, 28 avenue Doyen Lepine, F-69677, Lyon France
Téléphone	+33 (0)4 27 85 77 00
Email	vincent.cottin@chu-lyon.fr
Laboratoire	Inserm UMR754
Organisme	French National Institute for Health and Medical Research (Inserm)

Collaborations	
Participation à des projets, des réseaux, des consortiums	Yes
Précisions	Rare Pulmonary Diseases Healthcare Network RespiFil / European Reference Network ERN-LUNG

Financements	
Financements	Mixed
Précisions	Funded by the French « Investissements d'Avenir » cohorts programme, Grant « ANR » 10-COHO-0003. This study is also supported by industrial funding within the framework of a public-private partnership.

Gouvernance de la base de données	
Organisation(s) responsable(s) ou promoteur	French National Institute for Health and Medical Research (Inserm)
Statut de l'organisation	Secteur Public
Existence de comités scientifique ou de pilotage	Yes
Labellisations et évaluations de la base de données	Security audit certification of the database

Contact(s) supplémentaire(s)

Caractéristiques

Type de base de données

Type de base de données	Morbidity registers
Base de données issues d'enquêtes, précisions	Cohort study
Origine du recrutement des participants	A selection of health institutions and services
Critère de sélection des participants	Another treatment or procedure
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	The goal of the IIP/PID cohort is to include prevalent and incident IIP/PID cases diagnosed in paediatric patients and adult patients. For the prevalent cases and the retrospective nature of the data, a diagnosis validation will be required. Paediatric patient population Pediatric IIP/PID patients include all patients with diffuse parenchymal diseases linked to rare conditions others than immune deficiencies, proliferative disorders, metabolic disorders, and drug toxicity. Since the first description of the RespiRare IIP/PID paediatric cases, almost 400 patients (prevalent cases) have been included in the database. Around 60-80 new IIP/PID cases (incident cases) are currently reported per year. However, this number is underestimated, and will most likely increase with the identification of more adapted diagnostic criteria. Adult patient population For IIP/PID patients with IPF (approximately two thirds of the IIP/PID adult patients): considering the relatively large number of patients mainly aged and with a very poor prognosis, only prospective data will be collected to maximize the longitudinal collection of data and allow a detailed and accurate description of disease evolution in this population. For IIP/PID patients without IPF but with diffuse parenchymal diseases linked to rare conditions others than immune deficiencies, proliferative disorders, metabolic disorders, and drug toxicity

	(approximately one third of the IIP/PID adult patients): IIP/PID, incident cases and prevalent cases (with retrospective data) will be included in the cohort. About 2000 adult IIP/PID patients are expected to be recruited during this study.
Objectif de la base de données	
Objectif principal	Primary Objective The main objective is to describe the phenotypic features of the paediatric and adult patients with IIP/PID, at diagnosis and during the follow-up. These data will be critical for the description of the natural history of the various forms of IIP/PID. Secondary Objectives The secondary objectives are to: ? Identify gene factors involved in disease initiation and progression, ? Investigate the extent to which environmental and co-morbidity factors may influence disease severity and outcome ? Identify and validate biomarkers for disease diagnosis and progression Exploratory objectives ? Production of improved strategies for patient recruitment and enrolment into clinical trials ? Development of novel strategy for patient follow-up ? Development of novel diagnostic approaches ? Evaluation of effect on natural history of disease, and tolerance of therapy, in a large population in real life ? Development of novel therapeutic approaches Information Technology Objectives ? Develop and diffuse an electronic tool of data collection from various sources linked to a database integrating a system of management and follow-up of data-management allowing collection of data for IIP/PID paediatric and adult patients. ? Include data generated by patients and, where relevant, their parents and/or carers.
Critères d'inclusion	Patient with a diagnosis of IIP/PID IIP/PID diagnosis is established on presenting history, clinical, radiological and functional and if available pathological findings. Inclusion criteria include: Clinical criteria: chronic respiratory insufficiency manifestations including dyspnea/tachypnea,

	cough, and cyanosis during exercise or at rest Radiological criteria: characteristic chest High-Resolution Computed Tomography (HRCT) abnormalities including widespread ground glass or alveolar attenuation, reticulation often associated with traction bronchiectasis, and honeycombing Functional criteria: pulmonary function test abnormalities reflecting a restrictive pattern and including: loss of lung volume, vital capacity (VC), total lung capacity (TLC); reduction in the diffusion capacity of the lung for carbon monoxide (DLCO), gas exchange abnormalities, and altered ventilatory response to exercise Patients (parents/guardians for paediatric/patients) having given an informed consent to participate in the protocol Patients affiliated to the ?Regime National d'Assurance Maladie? Non-inclusion Criteria Patients with diffuse parenchymal lung diseases caused by drug toxicity, immunodeficiency, proliferative disorders including histiocytosis, and metabolic disorders Patients (parents/guardians for paediatric patient) not able to approve/understand the protocol
Type de population	
Age	Newborns (birth to 28 days) 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
Pathologie	J84 - Other interstitial pulmonary diseases
Sexe	Male Woman
Champ géographique	National
Détail du champ géographique	Complete national coverage through the network of rare pulmonary disease reference and ciompetence centers

Collecte

Dates

Année du premier recueil	2017
Année du dernier recueil	2021 minimum

Taille de la base de données

Taille de la base de données (en nombre d'individus)	[1000-10 000[individuals
Détail du nombre d'individus	2550

Données

Activité de la base	Current data collection
Type de données recueillies	Clinical data Declarative data Paraclinical data Biological data
Données cliniques, précisions	Direct physical measures Medical registration
Détail des données cliniques recueillies	The main variables collected include demographic aspects, family history, clinical examination results, environmental data, socio-professional details, patients' medical history, anatomopathological characteristics, biological, microbiological, and imaging tests. Both studies also involve bronchoscopic procedures, respiratory function measurements, disease progression monitoring, fertility data collection, genetic aspects, treatment records, quality of life questionnaires, and the inclusion of information on the Covid-19 episode.
Données déclaratives, précisions	Paper self-questionnaire Internet self-questionnaire Face to face interview
Détail des données déclaratives recueillies	SF36 or SF10 + St George's Hospital
Données biologiques, précisions	Record of biological results (hematology, biochemical, immunity, serology); Record of results for: bacteriology, virology, parasitology, mycology, bronchoscopy, bronchoalveolar lavage examination; Record of lung function tests, arterial blood gas and spirometry (If available sleep gas exchange and

	polysomnography); If available/performed, records of results for lung tissue examination, lung biopsy (surgical, transbronchial), lung explant; If available/performed, records of other organ function evaluation (including digestive and cardiac examinations)
Existence d'une biothèque	Yes
Contenu de la biothèque	Serum Fluids (saliva, urine, amniotic fluid, ?) Tissues DNA Others
Détail des éléments conservés	plus broncho alveolar liquids
Paramètres de santé étudiés	Health event/morbidity Health event/mortality Health care consumption and services Quality of life/health perception Others
Consommation de soins, précisions	Hospitalization Medical/paramedical consultation Medicines consumption
Qualité de vie/santé perçue, précisions	SF36 or SF10 + St George's Hospital
Modalités	
Mode de recueil des données	eCRF using REDCap; Cloud based, secure by design, web accessible platform. Certified Health Data Hosting resource
Nomenclatures employées	HPO, ICD10, Snomed CT, Orpha Codes and ORDO, Drug dictionary (DCIs)
Procédures qualité utilisées	Continuous data management; Data Management Plan and Data Validation Plan. Native controls and Query system
Suivi des participants	Yes
Modalités de suivi des participants	Monitoring by convocation of the participant Monitoring by contact with the referring doctor Monitoring by crossing with a medical-administrative database
Appariement avec des sources administratives	No

Valorisation et accès

Valorisation et accès

Accès

Existence d'un document qui répertorie les variables et les modalités de codage	Yes
Charte d'accès aux données (convention de mise à disposition, format de données et délais de mise à disposition)	Access requests to RaDiCo-PID data (rough / structured), biocollections or to analytic reports will be examined by the scientific committee following submission of a Specific Research Project (SRP) synopsis, as defined in the Resource Access Charter. Must be sent to pid@radico.fr
Accès aux données agrégées	Access on specific project only
Accès aux données individuelles	Access on specific project only